SALUD COLECTIVA, Buenos Aires, 7(2):174-176, May - August, 2011

Authors' response

Respuesta de los autores

***Ugalde**, Antonio[1]; **Homedes**, Núria[2]*

[1]*PhD in Sociology. Professor Emeritus of Sociology, University of Texas at Austin, USA. augalde@mail.utexas.edu*

[2]*MD, Doctor of Public Health. Professor, School of Public Health, University of Texas at Houston, USA. nhomedes@utep.ed*

Response to the commentaries of: Gonorazky SE; Tajer CD; Ferrante D; Martínez RA; Gómez-Vargas M; Lorenzo C, Garrafa V; Forcades i Vila T. Salud Colectiva. 2011;7(2):149-173.

We first must thank Salud Colectiva for taking the initiative to organize this debate regarding the ethical and human rights aspects of clinical trials conducted in Latin America. We also appreciate the opportunity to respond to the commentaries made by eight experts from different countries (Argentina, Brazil, Costa Rica and Spain) with different professional experience (members of independent and institutional ethics committees, principal researchers, activists, bioethicists, directors of regulatory agencies, academics, and executives of transnational pharmaceutical companies). This diversity of countries and perspectives has added to the depth of the debate.

As the goal is to seek solutions to the problems with clinical trials in Latin America, which according to the literature are not so different from the problems experienced in other low and middle income countries, we will try to weave together the ideas that we believe to be most important and that suggest solutions or criticize the ideas we have offered in our article (1).

The additional dichotomy deception/truth introduced by Marvin Gómez-Vargas (2) is important because, in short, the opacity and the barriers an external researcher faces in order to collect data, clarify doubts and verify that clinical trials are being conducted in accordance with the protocol and the ethics criteria accepted internationally are so large that they lead us to think that the industry has something important to hide. A first topic of discussion is how to prevent governments from allowing the phrase so frequently invoked by the industry – "we must protect industrial secrets" – to become an excuse for not protecting patients' rights, of both those who participate in clinical trials and those who take the drugs. Goméz-Vargas asserts, from his experience as a former executive in the industry that, more frequently than we imagine, clinical trials have mercantilist rather than scientific goals. Teresa Forcades i Vila, when citing Adriane Fugh-Berman's research on Wyeth (3 p.172), stresses this same point, which is also touched upon in the comments of Ricardo Martínez (4), Claudio Lorenzo y Volnei Garrafa (5), Sergio Gonorazky (6) and Daniel Ferrante (7). The statements of these authors as well as the decalogue proposed by Carlos Tajer (8) allow us to conclude that there is general consensus around the following: if the protection of industrial secrets implies lack of protection of human rights, it is necessary to look for alternatives to the implementation of clinical trials.

The origin of the problem is expressed clearly and succinctly in the words of Lorenzo and Garrafa when they indicate that "clinical trials are an eminently industrial activity, and like all company initiatives they are immersed in the power games of the free market" (5 p.167). We add that this power game is what leads to deception. Just a few days ago, the influential and conservative newspaper *Financial Times* included a section about the corruption of the transnational companies (9). A reading of this article allows us to assert that corruption is a practice almost inherent

SALUD COLECTIVA, Buenos Aires, 7(2):174-176, May - August, 2011

to the competitive characteristics of capitalism: the game of the companies is to beat the competition, and this requires being able to avoid the surveillance of the State. Furthermore, according to the author, the State has not shown great interest in detecting corruption; in the case of the US, only recently has the Department of the Treasury started to impose heavy fines on transnational corporations in order to generate the funds it needs. Among the multiple examples mentioned within this *Financial Times* article are found references to the pharmaceutical industry that, although producing substances necessary to human health, behaves exactly like the industries that produce consumer goods that are not life essential – thus the need for strict and uncompromising regulation by the State.

Carlos Daniel Tajer (8 p.152) states that: "it would be a mistake of equally negative consequences to assume that all is fraud, corruption and manipulation in multicentric clinical research." Unfortunately, the lack of transparency does not allow us to verify the magnitude and the frequency of fraudulent acts. It is evident that one must not assert that all is fraud simply because the industry does not allow itself to be studied; however, the responses of the other commentators and the existing literature, including documents that due to time restrictions neither the other authors nor we ourselves have been able to cite, allow us to state that such cases of fraud are not exceptional. In every issue of *Boletín Fármacos* (10) we have published cases of fraud and corruption on the part of the pharmaceutical industry, including clinical trials published in peer-reviewed journals and non-sensationalist press outlets.

We should avoid conspiratorial interpretations, but we certainly cannot deny what is suggested by the data. The results of US surveys that are carried out to gauge citizens' confidence in institutions are not all favorable to the pharmaceutical industry. Along with the tobacco industry, Big Pharma ranks next to the lowest position. It is the responsibility of the industry to dismantle the barriers established in complicity with the regulatory agencies – including the Food and Drug Administration and the European Medicines Agency – regarding how clinical trials are conducted. This would make it easier for independent researchers to understand the scope of fraud in existence. Gonorazky's contribution offers a good example of this point when he refers to the Clinical Trial Data Monitoring Committees and, if the space would have permitted, many more examples could have been mentioned.

The manipulations within clinical trials have helped contribute to the high level of distrust of what has been called "evidence-based medicine." Several of the commentaries mention frauds in the most prestigious medical publications. Is it possible to produce an evidence-based medicine if scientific journals are incapable of detecting fraud? Or is that perhaps – as it is suspected – they publish sponsored articles even when peer reviewers suggest that they should not be published? It is more and more difficult not only for the physicians but also for citizens to identify what part of the information available is scientific and what part corresponds to ideological, political and company interests or even the personal ambitions of certain researchers with little conscience.

As Tajer indicates (8), drugs have saved lives, but they have also played a part in ending them, for instance in the cases of rofecoxib (Vioxx), rosiglitazone (Avandia), and hormonal replacement therapy. The morbidity and mortality caused by approved drugs is increasing, among other reasons because society is becoming more and more medicalized. As Gómez-Vargas comments (2), many clinical trials do not seek to discover new products but rather to foment the use of drugs that do not benefit the patient, and which may produce more or less serious adverse effects. Ricardo Martínez suggests this same concept when he quotes Pignarre: "the chemistry of molecules "produces physiopathologies" categorized as diseases" (4 p.161); and in the process of curing these invented physiopathologies, secondary effects are generated.

Regarding the role of ethics committees and the need to more adequately train their members, we would like to make clear our agreement with the assertions of Lorenzo and Garrafa (5 p.169). We wrote that it is necessary for ethics committees to be able to differentiate between clinical trials of drugs that offer truly innovative therapies and those that only pursue economic goals. However, we did not state that trained ethics committees would be able to do so;

SALUD COLECTIVA, Buenos Aires, 7(2):174-176, May - August, 2011

in fact, we suspect just the opposite, but would have liked to carry out a research study to prove as much. Our position (1 p. 143) is that final approval must be given by a national committee, as is done in Brazil. In fact, we believe that in order to restore credibility to clinical trials, it is necessary for institutions independent from the industry to take responsibility for the design, implementation and analysis of the results of clinical trials. Furthermore, all trials should be approved by a national committee as well as by institutional committees. Currently, there exists a clear conflict of interest because clinical trial results have an economic impact on those who sponsor them and on the organizations they contract, including the Contract Research Organizations and private ethics committees.

It is important to foster debate regarding clinical trials among academics, civil society and political leaders. Salud Colectiva has helped to initiate such a debate. Indeed, there are numerous issues to discuss, several of which have been mentioned in this first endeavor:

- What should be done to ensure that trial participants understand the consent forms?
- What should or can civil society do in order to make regulatory agencies prioritize the protection of citizens' human rights over the interests of the industry, facilitate independent investigations of clinical trials and require transparency?
- What should the State do in order to make regulatory agencies transparent?
- What should the Latin American States do in order for local scientists to research and develop drugs that respond to local needs?
- Who should pay researchers that participate in trials and the members of the national ethics committee?
- Who should conduct clinical trials?

BIBLIOGRAPHIC REFERENCES

1. Ugalde A, Homedes N. Cuatro palabras sobre ensayos clínicos: ciencia/negocio, riesgo/beneficio. Salud Colectiva. 2011;7(2):135-148.

2. Gómez-Vargas M. Dos palabras más sobre ensayos clínicos: engaño/verdad, la anemia moral de la "Big Pharma". [Debate]. Salud Colectiva. 2011;7(2):163-165.

3. Forcades i Vila T. Otras cuatro palabras clave para analizar críticamente un ensayo clínico: hipótesis, realización, análisis y publicación. [Debate]. Salud Colectiva. 2011;7(2):171-173.

4. Martínez RA. Interpelando a los ensayos clínicos [Debate]. Salud Colectiva. 2011;7(2):160-162.

5. Lorenzo C, Garrafa V. Ensayos clínicos, Estado y sociedad: ¿dónde termina la ciencia y empieza el negocio? [Debate]. Salud Colectiva. 2011;7(2):166-170.

6. Gonorazky SE. Principio de precaución en investigación biomédica, seguridad, obligaciones post-investigación y eficacia terapéutica supuesta de las drogas experimentales. Violaciones a la dignidad de los pacientes. [Debate]. Salud Colectiva. 2011;7(2):149-151.

7. Ferrante D. Investigación clínica en América Latina y Argentina: ¿es tiempo de cambios? [Debate]. Salud Colectiva. 2011;7(2):157-159.

8. Tajer CD. Hacia la investigación clínica independiente en América Latina. Un comentario a "Cuatro palabras sobre ensayos clínicos". [Debate]. Salud Colectiva. 2011;7(2):152-156.

9. Sender H. Lines less blurred. Financial Times. 18 jul 2011:7.

10. Boletín Fármacos [Internet] c2010 [cited 27 jul 2011]. Available from: http://www.saludyfarmacos.org/boletin-farmacos/

CITATION

Ugalde A, Homedes N. Authors' response. [Debate]. Salud Colectiva. 2011;7(2):174-176.

This article was translated as a part of an interdepartmental collaboration between the Bachelor's Program in Sworn Translation of English Language and the Institute of Collective Health within the Universidad Nacional de Lanús. The article was translated by Irene Jiménez, reviewed by Pamela Vietri, and modified for publication by Vanessa Di Cecco.