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Gómez-Vargas, Marvin

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Two more words regarding clinical trials: *deception/truth*, the moral anemia of Big Pharma

Dos palabras más sobre ensayos clínicos:
engaño/verdad, la anemia moral de la "Big Pharma"

Gómez-Vargas, Marvin¹

¹PhD in Pharmacy, PhD in Biomedical Sciences. Professor of Pharmacology and Pharmaceutical Ethics, School of Pharmacy, Universidad de Ciencias Médicas (UCIMED); and Faculty of Medical Sciences, Universidad Latina de Costa Rica. Costa Rica. gomezvm@ucimed.com

Commentary on: Ugalde A, Homedes N. Four words regarding clinical trials: Science/profit, risks/benefits. *Salud Colectiva*. 2011;7(2):135-148.

In his condition of moral agent, how can any given person at any given time activate, to his own benefit and with a certain possibility of success, the abundant and powerful resources capable of producing good conscience? It is as if an unconditional rule were applied to exonerate from blame, a perverse law that states: act in such a way as that the maxim of your acts shall be to not feel guilty, no matter what you do.

Rafael A. Herra. *Autoengaño: Palabras para todos y sobre cada cual* (1)

One sometimes finds oneself reading articles that cause great satisfaction in their readers, even when they – or perhaps it is because they – seem to present more questions than answers. The article written by Dr. Antonio Ugalde and Dr. Núria Homedes (2) is without a doubt one of these types of articles.

The authors' initial assertion that "the covering up of ethical violations, errors, and even fraud is a tacit condition imposed by the industry in order to continue future clinical trials (2)" may at first glance seem a bit hyperbolic; it inevitably leads us to question and reflect upon its veracity. Is that really how it is? Is it true that pharmaceutical companies are so lacking in ethics and morality that they conceal errors committed during clinical trials and foster acts of fraud?

When we see that those involved in the implementation of clinical trials in Latin American countries (the employees of the pharmaceutical companies as well as their complicit counterparts, those who without a trace of shame present themselves in the public eye as "clinical researchers") continue to demonstrate behaviors that indicate a systematic lack of ethics and an increasing contempt for the most basic principles of morality and human decency, we have no choice but to continue along this path of analysis and reflection. In the chorus of voices worldwide that have that have spoken out with serious, well-founded, objective and courageous criticisms concerning the activities of the pharmaceutical industry, there is no doubt that Antonio Ugalde and Núria Homedes stand out alongside such well-known names as Marcia Angell, John Abramson and Jerry Avorn from the English-speaking world; as well as Miguel Jara and Juan Gervas, to mention just two names that come to mind from the Spanish-speaking world. But in order to move away from simple words of praise and admiration for the validity, relevance and pertinence of the arguments presented by Ugalde and Homedes, I would like to contribute some ideas that may serve as a complement to the debate at hand, centered on the "two more words" referred to in the title of this commentary, whose meanings are also conceived of dichotomously: *deception and truth*.

I would like to make reference to the overt deception with which pharmaceutical companies attempt to subjugate the medical profession, other health professionals, the ethics committees in charge of reviewing and approving the study protocols, and even the patients themselves, every time these companies express to the so-called researchers and the regulatory agencies *"the need"* to carry out *"another type"* of clinical studies. They refer to studies that go beyond those required of companies in order to obtain authorization to market their products. These *"post-commercialization"* studies, known as Phase IV studies, should in principle be subject to priorities concerning patient safety, such as searching for adverse effects of particular interest which were not clearly detected during the development phases. These studies are justifiable only when safety issues are involved and should be proposed only when the regulatory agencies or local health authorities consider it pertinent to carry out such studies.

The protocols of these studies are of poor scientific quality; written by medical marketing managers (usually physicians with more experience and training in business administration than in clinical medicine), their sole purpose is to support the business of the pharmaceutical industry. Most of these protocols are hybrid documents composed of information from other studies, with minimal changes when not explicitly copied from studies already conducted. With slight variations in their titles or in their basic designs, these *"new protocols"* are mere *"exercises"* of global marketing and promotion strategies. Their one and only purpose is to familiarize doctors identified as *"potential prescribers"* with the use of new drugs. According to the English terminology, these protocols are *"designed"* to provide *"hands-on experience"* to the so-called KOLs, *"key opinion leaders"* within the field in which the protocol will be carried out. The KOLs are specialized physicians the pharmaceutical companies have clearly classified within a *"ranking"* of relative importance in terms of the usefulness, the contribution and the special retributions by which those physicians safeguard the companies' interests, collaborating as lecturers, *"authors"* of the articles, potential *"researchers,"* or simply,

thanks to their reputation as well-known physicians who consistently prescribe the products of the company.

Frequently, the industry attempts to hide fact that these studies belong to Phase IV trials, instead classifying them with the dubious nomenclature of Phase III B studies so that they still appear to be development trials. The authorities responsible for enforcing ethical regulations and for approving research protocols in Latin American countries are not as organized as one would wish them to be. They also lack personnel capable of detecting the serious methodological flaws these protocols contain or of recognizing objectives that are not genuine to a Phase IV study.

Among those who work in the implementation of clinical trials persists the discourse that clinical trials do not just mean a benefit for trial participants, but for many participants represent the only resource at hand with which they may save their lives if they are suffering from a serious disease. Many professionals working for these companies have unconsciously developed mechanisms with which justify and excuse what they do in their jobs to themselves and to others. These individuals have a perception of what they do that is adapted so fully to their wishes and valued so closely in line with their personal interests, that it is hard to believe that their convictions are the product of their cynicism. This is something that escapes the understanding of any person with a minimum ability for analysis and reflection. But also there are people who do not deceive themselves: they know they are lying and they do it for a specific personal goal. This is why they consciously scorn and underestimate the few genuine pieces of information that can be derived from clinical trials and instead become architects of all types of marketing schemes. Ironically, these individuals occupy decision-making roles and are admired by their company peers for the acuity and efficacy of their business acumen. It is these scrupless individuals, usually medical managers or managers of business units, who make use of clinical trials findings (only the positive results, of course, because negative results are never published) to provide fraudulent explanations of pharmacological or physiopathological processes.

It is a severe offense against the authentic scientific spirit that these individuals take advantage of many health care professionals' desire for knowledge in order to instill and convey false information, concealing true facts or only partially expressing them and distorting concepts in order to obtain some sort of competitive advantage for themselves or for the company that employs them.

As long as money continues to be the primary incentive for the executives that work in pharmaceutical companies, there is very little hope they will one day make the altruistic and effective contributions they so claim to. As long as the unethical and amoral behaviors prevail over all others, no discourse of political correctness and sensitivity to the health needs of the population will redress the unpopularity these companies have gained. If, by chance, pharmaceutical industry executives were able to prioritize truth over deception, and tried to be honest with themselves and stop deceiving themselves with trite and sentimental slogans

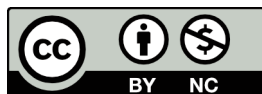
("We work for your health," "We innovate for your well-being," "Your family's health is our reason for being," among others), they would have to admit, at least, that veracity is incompatible with the practices of corporations whose main responsibility lies in maximizing their shareholders' profits, regardless of whether the company's activities satisfy a genuine health need. It is hard to believe that an industry that chooses to dedicate itself to the development of so-called "blockbuster" drugs for chronic diseases, and to what are now called "lifestyle" drugs for the treatment of baldness, obesity, shyness, erectile dysfunction, or to lengthen eyelashes and make nails more beautiful, can attain even a minimum of credibility, while millions of people in underdeveloped countries die as a result of the scant or nonexistent interest these companies show in developing drugs for the treatment of serious (but "forgotten") diseases that affect large populations from countries lacking a market able to afford such drugs.

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