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EDITORIAL

Marcos Bosi Ferraz

When should the physician question information disseminated by the pharmaceutical industry?

The act of prescribing any drug involves at least three interested parties: the drug manufacturer; the individual prescribing the drug; and the patient. In a simplistic way, all three participants in this process share a common interest in ameliorating or resolving the problem that caused the patient to seek medical attention. Other interests, not all of which will be common to each of these three participants, may be present consciously or unconsciously.

To obtain a licence for its commercialization, every drug must satisfy a series of norms that vary from country to country. These norms generally require documentation of the minimum and acceptable risk of serious or frequent side effects of the drug, as well as requiring it to be effective and efficacious within its proposed target population.

With the constant advance of technology, and the recognition that resources allotted to health care are finite and proportionally more and more scarce, there has been a recent tendency to require that a new drug be as, or more, efficient than those already available and commercialized. Some countries, such as Canada and Australia, already require that a new drug be shown to be economically superior to its competitors.

However rigorous that these norms regulating the approval of pharmaceutics may be, they are not even close to being sufficient to guarantee complete safety to each of the parties involved. The act of prescribing is extremely complex and involves the use of information which may particularize each clinical case. For a drug to be evaluated, it is necessary to have a minimum of information available to back up any analysis: it is necessary to have valid, scientific evidence.

Generating the evidence which permits the evaluation of the effectiveness, efficacy, and efficiency of the drug is also complex. At least three interested parties also participate in this process: the drug manufacturer, the researcher, and the patient. In this, the principal common interest is to contribute to the advance of science, while providing patients and health professionals alike with better means to reestablish the physical, social and mental well-being of the patient. In this process too, other interests, common to all three participants or not, may also be present consciously or unconsciously.

In the generation of this new knowledge, the three parties make investments and incur risks. The patient, being submitted to clinical research, however ethical and informed, is not exempt from risks.

The researcher, serving his objective of promoting the advance of science, has the responsibility, along with the medical and non-medical community, to plan, execute, and analyze the proposed research in the best possible way. The researcher's investment and risk is directly linked to the repercussions of each investigation, and to the effects of its results on his professional career.

Besides the concerns cited above, the pharmaceutical industry has an interest in maintaining its "business", or rather, the sale of a product that required a great investment and risk.

The patient, however interested in the improvement of his medical condition, in some instances values this condition for the indirect gains it provides. This fact cannot be neglected and should be evaluated and pondered in terms of the relationship established with the researcher and physician. The tendency of patients consciously or

unconsciously to appease the desires of researchers and physicians is widely known and documented.

At the conclusion of a research project, the researcher sets forth numerous reasons to publish the obtained results. These reasons may differ from the reasons that directed the reader to this scientific material. In other words, the motives behind the writing of an article do not always coincide with reasons that justify the reading of this article.

It is important to be aware that sometimes researchers write articles with the intention of obtaining recognition, respect, or fame in the scientific world, or perhaps to justify further articles and new research financing. These reasons alone would justify not reading a good proportion of published articles.

To make its "business" viable, the pharmaceutical industry must defend its interests, always in a responsible and ethical way. Some figures will illustrate the commercial interests which understandably accompany and stimulate the investments of the drug industry. For the research and development of a new drug, from the first studies with experimental, pharmacokinetic and pharmacodynamic models until its approval and sale, it is estimated that an average of US$100-250 million is invested per drug, in a process lasting from 10-15 years. Brazil is among the top 10 pharmaceutical markets in the world, with an annual turnover of US$6 billion. Here, the industry markets over 4500 products, and employs more than 50 000 people. As in other developing countries, less than a quarter of the Brazilian population consumes more than 60 percent of the medications produced. These figures by themselves make the business opportunities in this sector clear.

Besides the reasons cited previously, it is also important that we recognize that the medical establishment, even in developed countries, but principally in developing countries, is not adequately aware of, or trained to verify, the quality of publications, or rather, whether the evidence presented is scientifically valid.

Related to this fact, it is worth highlighting the speed at which new information arises. It is difficult for the specialist to keep himself up-to-date. For example, considering the year 1996 and consulting Medline for the terms "rheumatoid arthritis", "systemic lupus erythematosus", and "NSAIDS": respectively 1439, 740, and 226 published articles were found available to the medical establishment.

To keep updated, the physician must optimize his reading time. A useful strategy is the rejection of poor quality articles, thus allowing adequate time for a more careful reading of fewer articles, potentially valid scientifically and of use in his daily medical practice.

Nevertheless, it is extremely important that the physician should use the concept of evidence-based medicine in his daily work. To this end, it is to be hoped that there is critical evaluation of the research methodology utilized in every article. In the case of a clinical trial evaluating the effectiveness or efficacy of a drug or therapeutic intervention, it is fundamental that the following questions be answered:

- Was the division of patients into treatment groups truly randomized?
- Were all the clinically relevant parameters evaluated?
- Were the patients studied recognizably similar to yours?
- Were clinical and statistical significance considered?
- Is the therapeutic intervention executable in your environment?
- Were all patients who participated in the study considered in the conclusions?

In conclusion, as representatives of their patients' interests, physicians have the obligation to provide interventions recognized as being most effective, efficacious, and efficient. Therefore, a critical evaluation of the methodology of a publication must always be performed, independently of its source.