

Conflict of Interest and Collaboration between Science and Industry

Scott E. Walker

In September 2001 the members of the International Committee of Medical Journal Editors simultaneously announced a revision to the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals.”¹ The primary change was the addition of a statement that the editors of medical journals may choose not to review or publish articles for which a sponsor had sole control over the data or the power of veto on the decision to publish.

At first blush, this position seems trivial and far removed from the daily life of a pharmacist. How could a company decision to limit publication affect a pharmacist, especially one who is not involved in research? However, publication, and more specifically decisions about what is and is not published, directly affects one of the basic functions of pharmacists — supplying information. We devote time to keeping up with the literature, finding out what is current, and determining which information is accurate. This task can be difficult and may even be impossible if information is withheld or if only “approved” packets of information are released to us. The new conflict of interest statement in the Uniform Requirements is designed to combat these problems and could affect both how research is conducted and the type of information that eventually gets published. Thus, although industry support of research is laudable and necessary and must continue, a balance must be found between industry’s desire for confidentiality and researchers’ need for, and the right of access to, accurate, current, and complete information.

So why was this step necessary? For every industry-sponsored study, there is, in addition to the protocol, a confidentiality agreement. The right of access to accurate, current, and complete information can be restricted by such a confidentiality agreement or by a legal decision about who owns the data. Given the current level of industry-sponsored research, the

amount of information that could be withheld is potentially significant.

In a day and age when more scientists are producing more information than at any other time in history, it might seem surprising that a single study or piece of information could be regarded by any one group as so potentially catastrophic to their market that they feel it must be removed from public sight. However, the market for prescription drugs has become increasingly competitive, and companies must often focus on sometimes trivial differences to distinguish one drug from others in the same class. On this basis, companies may feel it necessary to control information about their products and, indeed, several have attempted to suppress study results. At least 2 examples have been described in detail. The case receiving the most Canadian press attention involved Dr. Nancy Olivieri, Apotex, and the iron chelator deferiprone or L1.^{2,3} A second case involved Knoll’s attempt to suppress publication of a thyroxine equivalence study.⁴ In both cases the pharmaceutical firm pointed to a signed contract stipulating that publication of any data required agreement from the sponsor for reasons of confidentiality.^{3,5}

If these were the only examples, there would probably be no need to change the guidelines governing manuscript submission. However, in a survey of 3394 life science faculty at the 50 universities that received the most National Institutes of Health funding, 410 respondents indicated that publication of their results had been delayed for more than 6 months at least once in the previous 3 years because of a financial consideration.⁶ The fact that manufacturers and some academics take steps to protect a financial interest should not be surprising. However, I am amazed at the lengths to which some manufacturers have gone to suppress publication. Suppression generally occurs



through the threat of legal action^{3,5} and has even involved pressure exerted on persons (for example, the chair of an Ontario Ministry of Health committee completing a class review of proton pump inhibitors⁷) or groups (for example, the Canadian Coordinating Office for Health Technology Assessment in relation to its class review of statins⁸) who complete third-party reviews. The most amazing story involves Herbert Needleman and the 20-year effort of the International Lead Zinc Research Organization to discredit his work concerning the effects of environmental lead on childhood development.⁹

The new rules that will govern publication in the most influential medical journals,¹ directly address the situation in which the sponsor wishes to publish a paper but would like to suppress some information, for example, that relating to side effects. However, they do not address the situation in which a manufacturer explicitly states from the outset that the data will never be published. Pure contract work will continue, and contract research organizations (CROs) will be set up to complete it, but investigators outside of the CRO sector will have to decide if they wish to participate in work that may never contribute to optimum patient care because the resulting publications will not disclose all of the study results.

I think that the September announcement serves at least 2 purposes. It is a notice to companies that contractual arrangements denying investigators the right to examine the data independently or to submit a manuscript for publication without first obtaining the consent of the sponsor are unacceptable.¹ It also serves as a reminder to investigators that they should protect their rights and insist that they be able to decide what should be published and that they have complete access to all of the data. Investigators are sometimes pleased to be given the opportunity to complete a research study, but a study that does not receive impartial analysis or for which the results are not completely disclosed produces no societal benefit. In such studies the risks of exposing patients to a procedure or drug most certainly outweigh

the benefits, and on these grounds some would argue that it is unethical to conduct the research. With this in mind, investigators should remember a statement credited to Benjamin Franklin: "To study, to finish, to publish".

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Scott E. Walker, MScPhm, FCSHP, is Co-ordinator, Research and Quality Control, Department of Pharmacy and Division of Clinical Pharmacology, Sunnybrook and Women's College Health Sciences Centre, and Associate Professor, Faculty of Pharmacy, University of Toronto, Toronto, Ontario. He is also the Editor of *CJHP*.

Address correspondence to:

Scott E. Walker
Department of Pharmacy
Sunnybrook and Women's College Health Sciences Centre
Room KB333
2075 Bayview Avenue
Toronto ON
M4N 3M5

e-mail: Scott.Walker@swchsc.on.ca

