Full-Disclosure in Industry-Sponsored Laboratory Medicine Research Studies: Statement by the Consortium of Laboratory Medicine Journal Editors

Scientific collaborations between industry and academia are a common practice in the medical research community. These relationships can be beneficial in terms of fostering innovation in diagnostic and treatment modalities that improve patient care. However, reports in the medical literature have highlighted the risks of such relationships by demonstrating a systematic bias in the study findings in favor of the sponsors. Therefore, the International Committee of Medical Journal Editors (ICMJE) issued several policies requiring investigators to deposit information about the clinical trial into a designated registry prior to patients' enrollment and authors to fully disclose all potential conflicts of interest at manuscript submission. Any step that increases transparency will help to safeguard the integrity of clinical research and maintain the trust of the general public in the medical institution.

Although most published reports questioning the integrity of industry-sponsored research have focused on randomized clinical trials of pharmaceuticals and other interventional modalities, similar problems are likely to exist in other areas of clinical research, including diagnostic and prognostic studies based on laboratory tests. In the laboratory medicine literature, some industry-sponsored studies lack information on manufacturers that is important for the reader to fully assess the value of the presented work. These studies include comparisons of the performance of tests or instruments from various manufacturers as well as presentation of standardization efforts. For example, the practice of not linking the identities of the different manufacturers to the specific assays compared in a study is in conflict with the openness of the current scientific publishing environment.

It is the responsibility of journal editors to assure full disclosure by the authors and complete transparency in presented information; this is essential to uphold the trust of the scientific community in their publications and of the general public in their profession. To that end, editors of the laboratory medicine journals listed below have established the Consortium of Laboratory Medicine Journal Editors (CLMJE), an entity that is similar to the ICMJE. The Consortium is meant to complement the efforts of the World Association of Medical Editors (WAME) and the Committee on Publication Ethics (COPE) by issuing guidelines and requirements that are specific to laboratory medicine issues. Assuring integrity of scientific publication is a complex task. In this jointly-published editorial, we wish to focus on the first step toward that goal, that of full-disclosure in industry-sponsored laboratory medicine studies. All participating journals have their own Conflict of Interest forms for authors to complete at submission or prior to publication of their reports. However, since not all these forms require delineation of the role(s) the funding sponsor had in the study, this point also will be addressed.

To facilitate full-disclosure in industry-sponsored laboratory medicine studies, it is expected that authors clearly indicate to the editor of the journal to which the work is being submitted the role of the funding sponsor in the design of the study, the analysis of the data, and the preparation of the manuscript. The editor may wish to publish this information in the manuscript.

It is also expected that when reporting comparison and standardization studies, the name of manufacturers of the examined tests or instruments will be linked with the data in the manuscript. This practice will enable readers to use the information on specific tests or instruments and to inform clinical users on the limitations that may influence clinical decisions based on the laboratory results. Authors may argue that such disclosure could discourage manufactures from participating in evaluation and standardization studies based on concern that the data could be unfairly used against their products. Clinical investigators and the pharmaceutical industry have put forth similar arguments when the issue of registering randomized clinical trials was presented; these fears proved to be unfounded. Moreover, anything short of full-disclosure and complete transparency should no longer be tolerated in the current scientific publishing environment. If authors sincerely believe that the scientific findings would be incorrectly interpreted based on such disclosure, they should articulate the appropriate use and limitations of the information in the text of the manuscript.

The members of CLMJE listed below will require compliance with these guidelines for publication in their respective journals. Although, the CLMJE does not include all laboratory medicine journals, the editors of all such journals are strongly encouraged to consider adopting these requirements. This Consortium fully acknowledges that such requirements are only the first step toward assuring integrity of published reports and will continue to work to safeguard the scientific publishing community in laboratory medicine from undesirable practices.

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