

Corporate-sponsored research contracts—an ethical minefield

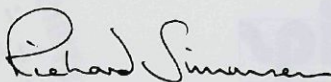
Is it appropriate for corporations to solicit outside agencies (such as universities) to carry out studies on their products and then to block publication of the data? On the one hand, one can clearly answer “yes.” If language is included in the contract (as it usually is) that either denotes a time period during which the manufacturer has the opportunity to study and raise questions about the data prior to publication, or if language is included that requires the manufacturer’s permission to publish, then the manufacturer clearly has the contractual right to question the data, or even to prevent publication of the study. Neither outcome, however, would give uninvolved parties cause for great confidence in corporate-sponsored research. If the data would have a clear impact on public health, is it not highly unethical for a manufacturer to put business interests ahead of the public interest by banning publication? As far as I know, no dental manufacturer has—yet—got into difficulties over the question of choosing business interests over the public interest—but a drug manufacturer certainly has.

A British pharmaceutical company and drugstore chain, Boots Co., recently suppressed publication of its own research that showed that one of its drugs could be replaced by a much less expensive generic version—a generic version that, the study’s author concluded, could cut US health care costs alone by \$356 million per year. It is a safe assumption, I think, that this not-insignificant amount would put almost as large a dent in Boots’ profits. The study was obviously commissioned with an expectation that the result would be the opposite and that the cheaper drug would be shown not to be as effective. Boots in fact chose a researcher who had previously published articles on the risk of switching patients from brand-name drugs of the same type as the Boots Co. drug to generic alternatives. At the time, Boots was in the process of selling its drug division for \$1.4 billion. Clearly, release of the data, which was already peer-reviewed and accepted by the *Journal of the American Medical Association*, with page proofs at the printer, would have negatively impacted the sales value of the drug division.

According to *The Wall Street Journal Europe*, at least five outside reviewers for JAMA, as well as internal and

external reviewers from the university where the study was conducted (the University of California at San Francisco), found the study valid and ready for publication. Despite this, Boots “aggressively strove to discredit [the study] and suppress its conclusions.” It makes me angry when the Boots executive who commissioned the study makes pompous, self-righteous statements, such as “I stopped a flawed study that would have put millions of patients at risk.” I am sure the Boots executive was more concerned with becoming the boss of the newly sold drug division, and with the state of his stock options, than with the health of millions of patients paying more than necessary for a drug. Clearly the executive’s self-interest is to suppress the truth and protect his, and his company’s, financial future.

Dental manufacturers should be encouraged to drop paragraphs in research contracts that restrict an investigator’s right to publish valid research data as soon as the study is complete and outside reviewers have determined that the study is not flawed and the data are valid. It goes without saying, I believe, that investigators should carefully read contracts and refuse to sign contracts that assign publication decisions to anyone but the researcher. If the manufacturer has done its homework and selected an ethical, competent researcher, and the researcher has done the work to appropriate standards such that the manuscript has been peer-reviewed and accepted, there should be no restriction on publication, except, perhaps, in the case of a material that has not been, or will not be, marketed, or where patent concerns need to be protected. To do otherwise is to foster suspicion of corporate-sponsored research as being somehow tainted and biased in favor of the manufacturer. It isn’t. So drop the self-serving publication restriction. The public interest, and corporate reputations, are at stake.



Richard J. Simonsen
 Editor-in-Chief