To the Editor:

Although Dr. Bodenheimer (May 18 issue) (1) makes a number of cogent observations about the sponsorship of clinical research by the pharmaceutical industry, his report lacks balance. As an employee of a contract-research organization (CRO), I have a different viewpoint.

Without providing supporting data, Dr. Bodenheimer concludes that drug trials conducted by CROs and other commercial entities are "heavily tipped toward industry interests" and that these organizations "will fail if they offend their funding sources." In fact, CROs have no vested or commercial interests in study outcomes. Such companies do not manufacture or sell pharmaceuticals, and the positive or negative result of any given clinical trial will not affect their financial well-being. Rather, the performance of CROs is judged by pharmaceutical and biotechnology companies on the basis of the quality of services provided: the degree of adherence to the protocol, governmental requirements, and agreed-on timelines; the ability to maintain professional working relationships with investigators, both academic and community-based; and the accuracy of the data. CROs are subject to audits by sponsoring companies, the Food and Drug Administration (FDA), and other regulatory agencies.

Dr. Bodenheimer also fails to note that several prominent academic medical centers have recently been criticized and even sanctioned by the FDA or by the Office for Protection from Research Risk because of deficiencies in the way in which clinical trials have been performed at these centers. (2,3,4) These deficiencies have included irregularities pertaining to the institutional review board, the failure to report adverse events, poor record keeping, inadequate protection of study participants, inadequate informed-consent procedures, and the fabrication of data. Putting more responsibility in the hands of academic medical centers will not guarantee that research practices will improve. Although investigators at academic institutions provide critical expertise in the development of new medicines, other organizations, such as CROs, can have important complementary roles.

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References

To the Editor:

I suggest three remedies to the problems identified by Dr. Bodenheimer. First, require all trials undertaken by pharmaceutical companies to be registered with the FDA, with end points specified in advance. Failure to register studies in advance would make their results inadmissible as evidence in FDA studies of efficacy. Second, make the pharmaceutical companies fill out a trial-completion report on all drugs that they have studied. Third, require the pharmaceutical companies to make the data from their trials available on a Web site for others to analyze. Appropriate means of protecting the subjects' confidentiality would be expected. Making the raw data available will allow others to analyze in depth the results of studies that the companies have chosen to ignore.

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Dr. Bodenheimer replies:

To the Editor:

Dr. Newman is correct that deficiencies have been uncovered in the performance of clinical trials by some academic medical centers. Moreover, many of the problems that I mentioned in my article regarding trial design, data analysis, control over publication, and authorship involve investigators at academic medical centers.

The root of these problems is a system of clinical drug trials that is dominated by funds from the pharmaceutical industry. The important question is, How can clinical-trial investigators -- whether in the commercial or the academic sector -- retain the highest degree of independence, so that the interpretation of their results is not skewed by the influence of the funding company?

I am not aware of studies that compare the validity of clinical-trial results from the commercial sector with the validity of those from the academic sector. However, commercial CROs are more dependent than academic medical centers on the pharmaceutical industry. CROs would not exist without drug-company money; academic...
medical centers receive most of their funds from other sources. The success of a CRO in a
highly competitive industry is based on its profit margins, which depend on securing
contracts with the pharmaceutical industry. In contrast, the success of an academic medical
center is based on its reputation for excellent patient care, teaching, and research work, with
much of its nonclinical research funded by the National Institutes of Health.

If CROs simply implemented studies that were designed, interpreted, and published by
pharmaceutical companies, then perhaps they would have no commercial interest in the
outcomes of the studies. However, a 1994 survey of pharmaceutical-industry sponsors of
research showed that 82 percent use CROs to write publications, 77 percent employ CROs
to do statistical analysis, and 29 percent contract with CROs to design studies. (1) These
activities have a major influence on the ways in which study outcomes are interpreted and
publicized, thereby giving CROs a clear commercial interest in interpreting outcomes in the
manner desired by their funders.

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References

1. Getz KA, Vogel JR. Achieving results with CROs: their evolving role in clinical

Return to Text