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Salim Yusuf (Hamilton)

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Look, no strings: publishing industry-funded research

World wide, pharmaceutical companies spend over US\$40 billion annually on research and development. The cost of getting a new drug to market is as much as US\$600 million.\(^1\) As costs have escalated, pharmaceutical companies have turned to contract research organizations; in the US, private research companies received 60% of pharmaceutical company research contracts last year. Gone are the days when clinical trials are conducted in the pure ether of academe by researchers whose investigations and careers are uninhibited (even if imperfectly) by the sponsor.

Pharmaceutical companies know that faulty or dishonest research leads down a long and costly road to drug withdrawals and lawsuits. Nevertheless, the pressure to come up with a winner — a drug that works and has an acceptable safety profile — is extreme. It should not surprise us when the inherent biases of research slide into deliberate distortion or the suppression of unwanted results.^{2,3}

Integrity in clinical research requires that investigators have complete intellectual independence in conducting their studies. But, so far, specific and enforceable guidelines to safeguard the scientific independence of researchers (and ultimately, the interests of patients) have not been codified. In the face of this policy vacuum, a group of Canadian investigators have proposed a set of "rules" to govern industry–university research contracts in Canada (see page 783).⁴

In a similar vein, the International Committee of Medical Journal Editors has adopted tough new policies governing the publication of industry- and government-sponsored research (see page 786). Henceforth these 11 leading journals will require authors to attest that they "had full access to all of the data in [the] study and ... [to] take complete responsibility for the integrity of the data and the accuracy of the data analysis." In addition, editors will retain the right to review the study protocol as

well as funding contracts for the study before accepting the paper for publication. *CMAJ* will not accept reports on research that was conducted under a contractual arrangement that did not meet these ethical standards.

Pharmaceutical companies have argued that information about a new drug's efficacy and safety is proprietary. We maintain that the ownership of such information is much broader: health research is a public good. People who volunteer to enrol in clinical trials do not intend the results of their participation to be distorted or suppressed. And the public has an additional interest in industry-funded research: as tax incentives and deductible expenses, about 70% of the costs are indirectly supported by the public purse.

In an ideal world, the necessary conditions for the disinterested conduct of research would be set by industrial sponsors themselves with fully articulated policies to ensure the scientific independence of the research they fund. No researcher should be expected to produce "findings" without full access to the data, freedom from interference in analysis and interpretation, and the liberty to publish all results, however disappointing to the shareholder they may be. In the meantime, investigators do well to arm themselves with rules for research partnerships, and editors to take on the role of watchdog. — CMAJ

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