Viewpoint

Rebuttal

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We are encouraged (but not surprised) that an investigator of Salim Yusuf’s stature and considerable experience in leading large multicentre international randomized controlled trials (RCTs) has not seen financial conflicts of interest in his dealings with industry.¹ These trials, as Yusuf notes, are robust enough to demonstrate real effects on the integrity of these studies.³,⁴ We agree with Yusuf that the drug approval process should be streamlined or improved. But that does not mean that one should not try to shed more light on the finances of clinical research. We argued, after all, for nothing radical: a consensus on appropriate physician remuneration in industry-sponsored clinical trials; clear, detailed and standardized budget templates; and greater transparency for all involved.

Yusuf argues that companies already have standardized budget formats in multicentre trials and cites inevitable variations among companies and countries as major problems. However, extant standardized budgets do not always have sufficient detail to indicate what services are being offered and the amount of remuneration for each service. Aware of these potential variations, we called for guidelines, templates, standardized categories, and a regional or international standardized clinical trial budget.⁵,⁶

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national consensus on appropriate compensation levels — not legalistic homogenization.

Yusuf also takes issue with our proposal to require research ethics boards (REBs) to approve not only the protocol, but also the study budgets. Yet because REBs are mandated to provide the necessary oversight to protect the health and well-being of the institution’s research subjects, it is imperative that they review trial budgets. Officials at institutions (e.g., research administration) may review more detailed trial budgets, but they are arguably conflicted in some cases, and in any event review by such officials is not a replacement for REB review.

As to disclosure to patients about financial remuneration, we view Yusuf’s position as paternalistic. If our proposal were followed, disclosure to research subjects would be straightforward: “The institution and the health care professionals involved in this clinical trial are being reimbursed for their services by the company that is funding the study (name of the sponsor), at the usual rates suggested by national guidelines for industry-sponsored clinical research.”

In sum, we have great respect for Yusuf’s global leadership in late-stage, academically driven multicentre trials and share his concerns about overregulation and bureaucracy. The hard fact, however, is that these big studies are the tip of the iceberg, focused largely on defining indications and market segmentation. Beneath the waterline is a very large volume of industry-sponsored trials of preap- proveal therapies, being performed in diverse clinical environments. Bringing the finances of these studies to light is in everyone’s interest.

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