Industry-driven Research: Have We Reached a Crisis Point?

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We know that all academic and private units are cash strapped. Money for research is dwindling and it is difficult to obtain new funds. Big industry is reluctant to donate money for research for various reasons, and new rules from the Department of Justice make it difficult to donate money directly to a department. We therefore cannot blame big companies for pursuing their own research. For one, it is cheaper; they already have the facilities. Above all, they are able to direct the research to their liking, which of course is profit driven. You cannot blame them.

Unfortunately, this presents a big dilemma to the practicing medical fraternity. When is it ethical to use a new (in my mind, still experimental) prosthesis? Does the recent ASR metal-on-metal prosthesis recall from DePuy ring a bell? I have not seen any alerts put out by other companies also producing metal-on-metal prostheses.

The British and Australian Hip Registries show a marked increase in revision rates of metal-on-metal cases as compared to cemented and noncemented cases. (By the way, both of these registries also show a higher revision rate for noncemented prostheses when compared to cemented hips.)

If you are a private or academic orthopedic surgeon, you may get a visit from a local representative of a big company, almost always accompanied by an “expert” on a new operation or procedure. The expert representative is polished and presents his material in an overwhelmingly convincing way. Offered the advantage of being sent to a special course and inundated with educational material, you are psychologically compelled to jump on the bandwagon. I do not blame the orthopedic surgeon in practice. Percentage-wise, very few are trained in critically evaluating research protocols, publishing research, and joining a valid new development.

The consequences are the possibility of a recall and of lawsuits, even against the surgeon. Why do huge, multinational companies risk losing hundreds of millions of dollars in class action lawsuits, or even risk going under? This has happened in the past and will probably happen in the future. The only answer is that the possibility of generating much higher profits in the future overrides reason and patient safety. It seems to me that in the absence of doctor-driven research, we should at least act as patient advocates as a corporate group. Remember, your name is also attached to disasters like these.

No new prosthesis or procedure should be undertaken by a practicing orthopedic specialist unless it forms part of a national/worldwide controlled trial sanctioned by a panel of national/international experts and the local Institutional Review Board.

What role should the American Academy of Orthopaedic Surgeons and overseas orthopedic associations play? They should publish guidelines for the orthopedic surgeon to adhere to before embarking on a new prosthesis or procedure.

The whole scenario also rewrites the relationship between you and the service providers. They should understand that you are a patient safety advocate. They are primarily in the business of generating money, regardless of what they say. If we cannot marry those 2 driving forces, patient safety should prevail.

It behooves us not to accept developer-published results but to look for independent researchers not driven by financial gain.

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doi: 10.3928/01477447-20110526-01