

## Short Communication

# Has the commercialisation of medical research gone too far?

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**Received:** 25 August 2015

**Revised:** 11 September 2015

**Accepted:** 12 September 2015

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### ABSTRACT

Government policy has been complicit in the increasing role of commercial companies in research, which in turn have little incentive to share the benefits of research. As a result, huge swathes of medical research rely on commercialisation and related patent protection in order to thrive. There is a distinct lack of evidence that commercialisation has led to an improvement in public health, the claim of increased innovation simply does not have empirical support. Commercialisation has led to skewed benefits in favour of companies, whereby industry is using the public's resource without adequately paying for it, this imbalance may be seen as a form of exploitation. In this paper I argue that the skewed relationship between commercial and public interest needs to be addressed in order to ensure we meet healthcare needs of our patients in the future and ensuring the healthcare remains affordable.

**Keywords:** Health research, Commercialisation, Funding

Medical research is increasingly dependent on commercial enterprise and the entrepreneurial paradigm whereby academia-industry-government is closely related continues grown in significance. As a result, huge swathes of medical research rely on commercialization and related patent protection in order to thrive. In the United Kingdom the government seems keen to encourage further commercialization and create entrepreneurial universities; I would argue that medical research has become too skewed in favor of commercial enterprise.

Government policy has been complicit in the increasing role of commercial companies in research, which often have little incentive to share the benefits of research. In the document 'Strategy for UK life sciences - 2011' it is clear the government wants to promote increased university-industry collaboration by providing 'incentives for people at all levels to develop scientific excellence'. The document makes little mention of ethical consideration, but instead commits to invest £310 million

in the 'commercialisation of research'. The monetary attraction of increased commercialisation is clear and industry itself is keen to promote the notion that they help promote patient outcomes and support economic growth.

Pharmaceutical companies have long argued that such a relationship is essential due to the high cost of research and development. Indeed bringing drugs to market is an expensive business with an average cost of \$800 million. No wonder the share of prescription drugs in the US has increased from 4.9% to 9.4% of total healthcare spending in the last 20 years. This argument at face value makes sense; the costs of research must be recouped from somewhere. However, history tells a slightly different story. In most of Europe only the process of producing a drug could be patented, not the drug itself, the rational being to reward the inventor without limiting further innovation. France introduced legislation allowing patents for drugs in 1967, Switzerland in 1977 and Italy in 1978. It must surely follow that most drug innovation occurred in countries such as the UK or the US, places

where patents were accepted. This was far from true, with thriving pharmaceutical industries in continental Europe during this period. Indeed patency law led to higher costs of medicines in the UK compared to Germany where patency was not permitted. There is evidence that even today patency increases costs of medicines. When patency protection was enforced on most of continental Europe the pharmaceutical industry in India grew exponentially (a country which had no patency protection), although more recently patency protection has been enforced on the Indian market.

The United Kingdom's Royal Society has said "uses of Intellectual property (IP) that benefit people in one part of the world but conspicuously fail to benefit others, or even act to their detriment, are not what the patency system is supposed to be about". For the developing world patents can restrict access to healthcare, with companies having little or no incentive to ensure their drugs are available to those with little financial resource. It was only when generic competition lowered the price for HIV antiretroviral drugs from \$15000 to \$99 that it became possible for those in the developing world to have access. The assertion that commercialisation and IP encourage innovation should be questioned. Innovation has never been dependent on patency. The chief scientific officer at Bristol Myers squib told the New York times 'more than 50 proteins exist that were possibly involved in cancer that the company was not working on because the patient holders either would not allow it or were demanding unreasonable royalties', restricting rather than furthering innovation. The National Institute of health care management reveals that over a period 1989-2000 54% of FDA approved drug applications contain active ingredients already in the market place. The change was in dosage, form or combinations of drugs. Around a third had new active ingredients but only a minority are an improvement over existing drugs on the market (238 out of 1035), so 77% are redundant. This would suggest that the \$800 million cost of bringing a drug to market is not a real investment in healthcare but instead driven by patency and the need to invent something. Let's not forget who pays for these costs, such wasted research increases the cost of healthcare for all.

A recent General Accounting Office study from the US noted a worrisome trend whereby research money is being pushed into innovations that can be patented, ignoring other possible treatment options. Such a system creates incentives that are not directly related to improvements in healthcare. Globally diseases such as TB, malaria and diarrhea account for 21% of the global disease burden but only get 0.31% of public funding.

There is a distinct lack of evidence that commercialisation has led to an improvement in public health, the claim of increased innovation due to commercialisation simply does not have empirical support. Commercialisation has led to skewed benefits in favor of companies, whereby industry is using the

public's resource without adequately paying for it, this imbalance may be seen as a form of exploitation. Ensuring equality is a basic principle and commercial companies must do more in order to avoid the charge of exploitation. Substantial profits are made from intangible contributions. This disparity is worse in the countries without universal healthcare and the principle of distributive justice is threatened.

Alternatives to the patency system are the nonexclusive licensing practices demonstrated by the Not for Profit Drugs for Neglected Diseases Initiative. This incentive funds research and offers the outcome on a nonexclusive basis to generic producers and allows the supply to developing countries at a reduced price. The Universities Allied for Essential Medicines Programme places conditions upon manufacturers that they must provide the drug in question to poorer countries for the lowest price possible. Offering financial rewards to not for those who create new medicines or advance life sciences is another alternative, although unproven to date. Proponents of a royalty's scheme claim it would help redress the imbalance between private and public interest. Another alternative would be to use the existing patency system more wisely, being more willing to reject patents if a drug is not a true advancement or comparable with current therapy. There is evidence that government agencies are captured by the private sector they regulate, especially in the context of cofounded research and licensing of subsequent products. We should question whether the benefits of research are truly shared amongst the public when between 1998 and 2002 the budget for research has doubled yet healthcare became increasingly unaffordable to large swathes of the world. This skewed relationship between commercial and public interest needs to be addressed in order to ensure we meet the healthcare needs of our patients in the future and ensuring that not the healthcare remains affordable.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: Not required*

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**Cite this article as:** Barker I. Has the commercialisation of medical research gone too far?. *Int J Res Med Sci* 2015;3:2841-3.