Commercialization and Stem Cell Research: A Review of Emerging Issues

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ABSTRACT

Stem cell researchers face pressure to develop therapies that will reach the clinic within a short period of time. Yet, this pressure may be unrealistic, as bringing stem cell innovations to the clinic will likely require significant time and financial investment. In a variety of biomedical fields, some evidence suggests that commercialization pressures and strategies may negatively impact research. These negative impacts may also be felt in the field of stem cell research, unless the challenges and issues are addressed in the design and implementation of commercialization policies. Further inquiry into the impact of commercialization on the field of stem cell research is required.

INTRODUCTION

Research into biomedical and scientific innovations has the potential to yield economic and health benefits. However, significant financial investment is required to bring these innovations from “bench to bedside” [1,2]. As such, it is no surprise that many governments and funding agencies believe that fostering commercialization is necessary to realize the economic and medical potential of biomedical research and to deliver on promised targets and benefits [2–5,101]. Indeed, the prevalence and intensity of commercialization pressure seems to have increased in recent years [6–10]. In this context, “commercialization” is defined as “both links [between publicly funded

researchers and] industry and efforts to turn university-based research into marketable products and services” [6,11].

The field of stem cell research in particular has been subject to significant commercialization pressure. Scientists face pressure from funding agencies and the public to develop stem cell therapies that will reach the clinic within a short period [12,13,102,103]. A recent survey of stem cell researchers found that 88% of respondents felt “moderate” or “intense” pressure to create clinical applications from their work [14]. To date, there has been only limited success in translating stem cell research into clinical therapies, but this has not dampened expectations in, or enthusiasm for, the field, as the phenomenon of “stem cell tourism” attests [12,13]. The commercialization pressures facing stem cell

researchers are likely to continue into the foreseeable future.

This article provides a brief overview of issues associated with commercialization and stem cell research. We highlight some commercialization policies in this field and discuss concerns and issues that may arise in research environments facing significant commercialization pressure. Commercialization is likely to be a valuable and essential tool in translating biomedical research, and stem cell research in particular, into viable clinical therapies. The benefits of commercialization strategies include more rapid translation of research into clinical products and greater overall investment in stem cell research [4,12]. Indeed, for many stem cell innovations, links with industry are essential for the translation and dissemination process. However, as we discuss below, there are

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challenges associated with commercialization, challenges that are often not discussed in policy documents that promote commercialization. What is needed, then, are policies that contemplate and address these challenges and allow commercialization to occur in an optimal manner.

Institutionalization of commercialization pressure

The pressure to commercialize biomedical research has become “institutionalized as a formal funding policy” [6]. It can be found in “both soft ‘nudges’ (expressed in policy statements, university technology transfer office (TTO) mandates and practices, funding opportunities, and intellectual property (IP) ‘toolkits’ available to researchers), and hard obligations (expressed in research networks and public funding agency requirements and agreements)” [11]. For example, commercialization expectations are now part-and-parcel of many research grants, which may require scientists to establish economic benefits and outcomes of their work in order to receive funding [6,7,104].

In the field of stem cell research, the institutionalization of this pressure is readily apparent from a brief survey of relevant programs and policies in a number of different countries. In Canada, the mission of the Stem Cell Network—one of the publicly funded Networks of Centres of Excellence, a program developed “to cultivate... ‘research partnerships between academia, industry, government and not-for-profit organizations’”—is to “act as a catalyst for enabling translation of stem cell research into clinical applications, commercial products, or public policy” [6,105]. In 2013–2014, the Stem Cell Network will fund a Commercialization Impact Grant that is “aimed at projects that generate novel technologies and intellectual property that have commercial value in the stem cell research or therapeutics markets” [106]. In the United Kingdom, the Medical Research

Council and the Technology Strategy Board (and institutions that it funds, such as the Cell Therapy Catapult) provide grants for projects that will stimulate economic growth and improve healthcare [107]. The National Health and Medical Research Council in Australia provides grants to a similar end for health technologies that show potential for commercialization [108]. The technology transfer program of the U.S. National Institutes of Health funds projects designed to “convert basic research ideas into commercially viable products and services” [109]. In Japan, recent allocations of funding for stem cell research have been tied to commercial, industrial, and clinical applications, with the expectation that they will contribute to economic growth [15].

Issues associated with commercialization

The potential benefits of commercialization, including increased revenue for research and development, increased profit, speedier product development, and knowledge translation, have been discussed elsewhere and will not be reviewed here, except to note that it is unclear

whether commercialization policies will achieve all of these objectives [6,7,9,11,16].

Although many commentators have discussed the potential problems associated with the recent commercial trends in biomedical research generally, less attention has been paid to the potentially negative effects of commercialization on stem cell research [12]. More research is needed into how commercialization impacts this field. We briefly review potential issues associated with commercialization policies, discussing evidence relating to stem cell research specifically, where available.

Commercialization may negatively impact research in a number of different ways. Commercialization “can skew the research agenda” of university researchers [17,18,104]. Industry partners may pressure scientists to concentrate on potentially marketable products and therapies, at the expense of “basic, curiosity-driven research” [104]. Additionally, industry–academic partnerships could create conflicts of interest that affect research [19]. For example, studies suggest that industry funding is associated with pro-industry findings [19,20]. The desire to get profitable therapies to the clinic quickly could lead to unsafe

Brief Look at Pros and Cons of Commercialization of Stem Cell Research

Benefits of Commercialization	Issues with Commercialization
Increased revenue for research and development	Can skew the research agenda of university researchers
Increased profit	Industry partners may pressure scientists to concentrate on potentially marketable products and therapies solely for that reason
Speedier product development	Could create conflicts of interest that affect research
Faster knowledge translation	May conflict with values of open science
Is a necessary component to capitalize on the economic, scientific, and medical potential of stem cell research	Could negatively affect collaboration
	Public trust could be diminished
	Targets set by commercialization policies may not be realistic

or unethical clinical trials, though this risk will hopefully be kept in check by the oversight of research ethics bodies [21].

Additionally, commercialization may conflict with the values of open science (the “movement...to openly share scientific knowledge and to forge models of ‘open scientific collaboration’”) [11]. There is evidence that “industry funding is associated with increased secrecy” [22]. Other studies suggest that “commercialization may be associated with data withholding and delayed publication” [12,16,21–29]. Additionally, some evidence indicates that commercialization negatively affects collaboration. For example, a recent study looking at collaboration among stem cell researchers found that “commercialization activity, measured by the number of patents, negatively impacted the degree of collaboration that results in published research” [30].

Furthermore, public trust in stem cell research and scientists who conduct this research may be diminished under aggressive commercialization policies. A large body of evidence indicates that public trust in science decreases when research is funded or conducted by industry [31,110]. Studies that have looked at the field of stem cell research specifically have similarly found that the involvement of private entities is associated with decreased public trust in stem cell science and scientists [32,33]. Given the public interest in this field and the importance of public trust in securing research participation, the impact of commercialization on public trust is particularly relevant.

Finally, expectations created by commercialization policies may not be realistic. Despite enthusiasm for stem cell research, few therapies have reached the clinic and research has not yet resulted in profitable products or significant economic benefits [1,12,34–36]. Skeptical about the profitability of these technologies, industry has been reluctant to invest [1,12]. The high-profile withdrawal of Geron, one of the few companies performing clinical trials with human embryonic stem cells, from

stem cell research is demonstrative of this concern [37].

CONCLUSION

In other fields of scientific research, studies suggest that commercialization policies come at a cost, including the potential to negatively impact research and to undermine public trust in researchers and science. Although there is a lack of data on the impact of commercialization on stem cell research in particular, it seems likely that the same issues experienced in other areas of biomedical research will accompany the push to commercialize stem cell research. Further inquiry is needed to determine how commercialization pressures impact stem cell research.

Despite enthusiasm for stem cell research, few therapies have reached the clinic and research has not yet resulted in profitable products.

To capitalize on the economic, scientific, and medical potential of stem cell research, it is increasingly apparent that commercialization, including productive partnerships with industry, is both necessary and inevitable. This article has highlighted issues with commercialization not to denigrate that reality, but to emphasize that, to be effective, commercialization policies must be developed in a way that effectively addresses those

issues in a constructive, sustainable, and empirically sound manner. Further research is needed to determine how to harness the benefits of commercialization in the field of stem cell research, while maintaining both the integrity of and public confidence in the research.

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