

The institutional workers of biomedical science: Legitimizing academic entrepreneurship and obscuring conflicts of interest

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Abstract

Given growing initiatives incentivizing academic researchers to engage in 'entrepreneurial' activities, this article examines how these academic entrepreneurs claim value in their entrepreneurial engagements, and navigate concerns related to conflicts of interest. Using data from qualitative interviews with twenty-four academic entrepreneurs in Canada, we show how these scientists value entrepreneurial activities for providing financial and intellectual resources to academic science, as well as for their potential to create impact through translation. Simultaneously, these scientists claimed to maintain academic norms of disinterested science and avoid conflicts of interest. Using theories of institutional work, we demonstrate how entrepreneurial scientists engage in processes of institutional change-through-maintenance, drawing on the maintenance of academic norms as institutional resources to legitimize entrepreneurial activities. As entrepreneurial scientists work to legitimize new zones of academic scientific practice, there is a need to carefully regulate and scrutinize these activities so that their potential harms do not become obscured.

Key words: institutional work; academic entrepreneurship; conflict of interest; entrepreneurial science.

1. Introduction

In a time of increasing commitments of universities—and the scientists that reside within them—to entrepreneurship and entrepreneurial science, this study seeks to examine how 'academic entrepreneurs' conducting biomedical research in Canada value these activities, and how this in turn may be reshaping the institutions of academic science. Academic entrepreneurship in the biomedical sciences has been increasingly encouraged and facilitated by a number of health and innovation policy initiatives at governmental and organizational levels in Canada (Brimacombe 2005; Canadian Institutes of Health Research 2006; Industry Canada 2007; Jenkins et al. 2012; Metcalfe 2010; Rasmussen 2008) and internationally, where claims have been made that these pursuits will yield social, economic, and health impacts (Etzkowitz 2008; Etzkowitz and Webster 1998). Yet, activities that involve commercial interests in the results of research and ties to private industry have also been met with concern by a somewhat different policy community for

their potential to cause conflicts of interest for the scientists that engage in them. Among these pushes and pulls around the involvement of academic biomedical scientists in entrepreneurial activities, little empirical attention has been given to how and why academic scientists value entrepreneurial activities, *alongside* concerns about conflicts of interest. By positioning academic entrepreneurs as agentic institutional workers, located within academic research organizations but working on entrepreneurial projects, we examine how these scientists work to legitimize entrepreneurial activities through the obfuscation of concerns about conflicts of interest, and claims about adherence to traditional academic norms, values, and activities. Specifically, we seek to examine how it is that academic entrepreneurs value the activities of entrepreneurial science that they pursue, and how they understand the potential for conflicts of interest to arise as a result of these activities. By using the lens of institutional work (Lawrence et al. 2011) to understand these valuations and understandings, we take academic entrepreneurs as institutional

workers who can interact with the institutions of academic science to introduce change, or to maintain these institutions through their practices, values, and actions.

A landmark study on ‘academic capitalism’ by [Slaughter and Leslie \(1997\)](#) found Canada to be somewhat resistant to the forces that led other English-speaking countries (USA, UK, and Australia) to adopt national-level policies about technology and economic development through academic entrepreneurship, though a more recent analysis found Canada to be ‘no longer the exception’ ([Metcalfe 2010](#)). And yet, despite the proliferation of policy and organizational initiatives and incentives for academic entrepreneurship in upstream biomedical science in Canada, there has been a lack of overall policy concern and attention to their potential harms or detriments ([Downie and Herder 2007](#)). This study thus examines the ways in which publicly-funded academic biomedical scientists in Canada value entrepreneurial initiatives, and explores how academic entrepreneurs engage in normative institutional work processes to reshape domains of academic scientific practice, and work to legitimize entrepreneurial activities in the face of concerns about the harms of these activities, related to the potential for conflicts of interest. Value here is understood both as the individual valuations and motivations espoused by academic scientists for engaging in entrepreneurial activities, and the social, institutional, and normative value that scientists perceive within entrepreneurial activities. Many studies have examined the rationales of scientists for their participation in entrepreneurial activities, and general trends toward the marketization or industrialization of academic science, and a somewhat separate body of literature has conceptually examined the proposed problem of conflicts of interest when industrial or entrepreneurial interests are present in academic research. However, limited scholarship has specifically examined the responses of scientists to these dual narratives by both examining their motivations and values related to entrepreneurial science, and also their understandings and management of potential conflicts of interest as they participate in these pursuits. This study thus addresses this research gap by examining both the values of academic scientists in undertaking entrepreneurial initiatives, and also their responses to the proposed problem of conflict of interest, and how these interact with each other in the context of institutional changes in academic science. By focusing on the normative orientations of scientists in relation to entrepreneurial activities and the potential for conflict of interest, this study examines how individual actors can initiate institutional change in academic science through their values, normative orientations, and responses to both entrepreneurial impetuses and conflict of interest concerns.

1.1 The rise of entrepreneurial science

A wealth of scholarship has explored ‘entrepreneurial science’ or ‘academic entrepreneurship’, understood as the activities undertaken by academic scientists to push their research to market applications through commercialization activities, as well as associated collaborations with industry ([Perkmann et al. 2013](#)). The emergence of entrepreneurial science tends to be characterized as a divergent set of activities, norms, and practices to those normally understood as academic science. Though some have found this distinction to be overstated ([Sauermann and Stephan 2013](#)), there is an implicit distinction or tension between the norms and activities that comprise the institution of academic science, and the institution of entrepreneurial or industrial science. As such, the introduction of

entrepreneurial activities into academic scientific practice represents, and is represented as, a novel or distinctive way of doing science.

The term ‘academic entrepreneurship’ has been used in a number of ways to describe a variety of activities involving interactions between the academy and the marketplace ([Mars and Rios-Aguilar 2010](#)). We characterize this term in its broadest sense, as both activities of research commercialization, including patenting, spin-off company formation, and technology transfer activities, as well as activities of collaboration with industry and the pursuit of industry-sponsored research. Given that both of these broad types of activities involve technology transfer and the derivation of commercial benefit from academic science ([Jain et al. 2009](#)), we use this broad definition of academic entrepreneurship. We do, however, recognize that different forms and modalities of academic entrepreneurship and engagement with the market entail different commitments from scientists, and that scientists may participate in them for different reasons ([D’Este and Perkmann 2011](#); [Perkmann et al. 2013](#)).

Internationally, trends indicate that academic scientists’ participation in entrepreneurial activities has been increasing, and a large, diverse body of scholarship has addressed factors, attitudes, and norms associated with these initiatives ([Grimaldi et al. 2011](#); [Landstrom et al. 2012](#); [Rothaermel et al. 2007](#)). These literatures have characterized the implications of entrepreneurial activities for society and the public interest, and described the ways in which academic entrepreneurship can facilitate societal ends. Much of this literature is premised on the benefits of these activities as a contribution to knowledge economies, and has drawn on the proposed benefits of a so-called *triple-helix* of academic–university–industry engagement ([Etzkowitz 2008](#); [Etzkowitz and Leydesdorff 2000](#); [Etzkowitz and Webster 1998](#)). Alongside the triple-helix model, other models have proposed a closer interaction between science and scientists and the needs of society. These models include Mode II science, which called for application-oriented and socially-distributed science ([Nowotny et al. 2003](#)), as well as calls for increased public engagement in scientific practices, and user engagement and translation as an aspect of scientific research. Others have been more critical of these developments, and noted an *asymmetrical convergence*, where the norms and practices of industrial science have taken dominance over those of academic science when the two come together ([Kleinman and Vallas 2001](#)). Indeed, initiatives that have promoted a market focus in academic research have been described as fundamentally changing the role of universities in society from structures that serve the public interest to organizations that operate for private profit and financial gain ([Bok 2003](#); [Krimsky 2003](#)).

Studies examining scientists’ motivations to participate in entrepreneurial activities have found that scientists engage in entrepreneurial activities to learn the skills of industry research and access funding and other in-kind resources from industry ([Baldini et al. 2007](#); [D’Este et al. 2012](#); [D’Este and Perkmann 2011](#)), as well as to gain perceived benefits for graduate students and research organizations ([Crespo and Dridi 2007](#)). Academic scientists also engage in entrepreneurial activities for reputational rewards and intrinsic satisfaction ([Lam 2011](#)), and have indicated that patenting is important to gain prestige ([Baldini et al. 2007](#)), or to protect their research and advance drug development ([Owen-Smith and Powell 2001](#)). The initiation of spin-off companies has been valued for accessing academic funding opportunities and research resources, as well as generating national economic and societal impacts ([Fini et al. 2009](#)).

While these studies, as well as much of the other literature on academic entrepreneurship and the shifting nature of academic

science has used the case of biomedicine or the life sciences as an illustrative example, little of this scholarship has directly engaged with the *health* orientations and implications of the science being conducted (French and Miller 2012). The limited body of literature on academic entrepreneurship in health examines the pathways of health innovation from ‘bench to bedside’, as well as the organizational conditions and actions of agents in the unique health context of biomedical innovation. Many of these scholars have called for the recognition and management of potential harms alongside fostering and allowing for the productive benefits of entrepreneurial activities (Gelijns and Thier 2002; Nelson and Bierer 2011; Taylor 2013). Because entrepreneurial activities in the biomedical sciences can ‘fall down the cracks between health policy and science policy’ (Atkinson-Grosjean 2005:193), there is a need to examine how the promises and concerns of health research impact the practices of entrepreneurial science, and how scientists engage with these issues.

1.2 The concern of conflicts of interest

Largely unconnected to the bodies of literature that describe and characterize academic entrepreneurship in biomedicine, medicolegal and bioethics scholars have cautioned against commercial interests and close ties to industry in publicly-funded, academic research, for their potential to cause deleterious conflicts of interest for academic scientists. Conflicts of interest in industry-sponsored or market-driven research are caused when ‘a primary interest (such as validity of research) may be influenced by a secondary interest (such as financial gain or personal relationships)’ (Bero 2017: 1723). Academic scientists are said to be at risk of being in situations of conflicts of interest when industry-based or commercial interests overtake their academic or public interests (Bekelman et al. 2003; Hampson et al. 2008; Lemmens and Luther 2008; Tereskerz 2003), and cause them to conduct research that promotes profit and overlooks public benefit, and generally promotes bias within research processes, potentially causing harm to patients and the public (Baim et al. 2007; Bekelman et al. 2003). By these definitions, the risk of conflict of interest for academic entrepreneurs, either engaged in research commercialization activities or collaborations with industry, exists when industrial financial interests or personal gain may influence scientific interests, leading to bias in research processes and downstream harms or consequences.

Yet, the term *conflict of interest* itself tends to be associated with negative and harmful connotations, where industry or private sector involvement among academic scientists has been described as corrupting research agendas or causing bias in research processes and instances of research misconduct (Williams-Jones 2011). While the term itself does not imply instances of research misconduct, understandings and perceptions surrounding the construct of conflict of interest tend to associate these situations with research corruption and malfeasance. We thus take conflicts of interest to be both practical situations, where interests or practices may come into conflict, and also constructs with negative connotations that tend to be associated with research misconduct. While much attention has been given to the potential for conflicts of interest when financial or industrial interests overtake academic or public interests in clinical research (Angell 2008; Boyd et al. 2003; Miller and Brody 2005; Morin et al. 2002), there has been less attention to these concerns in the basic biomedical sciences. As basic biomedical scientists increasingly engage in industry-sponsored research and commercialization activities, concerns related to conflict of interest in this area remain

salient, though they may differ due to the more distant proximity to patient populations.

Empirical studies on conflicts of interest across the spectrum indicate that academic scientists themselves tend not to recognize conflicts of interest in their own activities and engagements. It has been shown that scientists involved in relationships with industry maintain confidence in their own ability and discretion in managing these relationships, and support self-regulation of these industrial ties (Boyd et al. 2003). As well, scientists or physicians who hold ties to industry tend not to disclose them because they assert a lack of relatedness between industry-funded projects and their academic or clinical presentations (Okike et al. 2009). Similarly, university leadership tends not to recognize their relationships with industry as creating any conflict (Campbell et al. 2004), and authors of clinical practice guidelines believe that industry ties would influence the recommendation of others, but not their own recommendations (Choudhry et al. 2002).

This distancing between scientists and ethical concerns, in this case those related to conflicts of interest, has been described as ‘ethical boundary-work’, wherein scientists delineate the ethical spaces in which they operate, and separate these scientific practices from ‘less ethical’ positions (Wainwright et al. 2006). This ethical boundary-work can involve processes in which scientists contrast their own practices with those of less ethical others, often to justify controversial research methods (Hobson-West 2012). Scientists working in contentious or contested biomedical research areas that may be perceived as causing ethical issues in the conduct of their research, such as those that may entail potential conflicts of interest, tend to be aware of the potential controversy surrounding their research, yet distance their individual practices from controversial ones. Ethical boundary-work can thus entail scientists’ shaping of their research practices in response to proposed ethical issues or controversies (Brosnan et al. 2013).

Drawing from this characterization of ethical boundary-work, this study takes ‘conflict of interest’ as (1) a potential problem of entrepreneurial science; (2) a construct imbued with ethical meaning, associated with research misconduct; and (3) a proposed situation that can organize scientific practices and scientists’ orientations to their laboratories as scientists may attempt to distance themselves from these situations. Conflict of interest, and the potential outcome of bias in research associated with this term, is thus not understood here as the necessarily harmful implication of academic–industry relations, as much of the literature on conflict of interest in clinical settings takes it to be, but instead aims to test the normative significance of this construct for entrepreneurial scientists, and understand how this construct can shape or be shaped by their normative valuations of academic entrepreneurs.

1.3 The institutional work lens

Drawing from scholarship that describes entrepreneurial science and academic researchers’ motivations to participate in these activities, studies that attend to the health implications and orientations of biomedical science, the concerns raised about conflicts of interest, and the evidence that potentially ‘conflicted’ researchers may not recognize these conflicts in their own practice, this study aims to focus on the actions and values of entrepreneurial scientists in order to examine how their values and orientations related to entrepreneurial science interact with the institutions of academic scientific practice. To do this, we draw from Lawrence et al.’s (2011) theories of institutional work, which can be used to examine how institutions are

‘worked out on the ground, in the day-to-day behaviours and experiences of actors’ (Zilber 2013: 82).

Institutional work examines the ‘action of individuals and organizations aimed at creating, maintaining or disrupting institutions’ (Lawrence et al. 2011: 1), and focuses on the *activities* of agents who are embedded within institutions and whose activities serve to create, maintain, or disrupt these institutions, rather than the *accomplishments* of institutionalization (Lawrence et al. 2009). This approach highlights the role of institutional actors as purposive and skilled institutional agents, as well as the ways in which their practices interact with institutions, thus capturing both agency and structure (Zilber 2013). These theories do not only account for grand changes in institutions, or the processes by which these are created, but also to the processes of institutional maintenance or disruption (Lawrence et al. 2009, 2011; Suddaby 2010).

Institutional work focuses on actors’ engagements with organizational and institutional legitimacy, taking legitimacy as core to the process of the institutionalization of new rules, norms, actions, activities, or logics. Legitimacy is critical to institutional work processes, as actors must negotiate the legitimacy of their actions, norms, and modes of working in order to change or maintain the institutions within which they are situated. Legitimacy, by means of social acceptability and credibility, is a requirement for actors within organizations to survive, and ‘is not a commodity to be possessed or exchanged, but rather a condition reflecting perceived consonance with relevant rules and laws, normative support, or alignment with cultural-cognitive frameworks’ (Scott 2008: 59–60). Legitimacy, by this definition, is also a resource for actors and organizations, one of social acceptability, needed for organizations to survive and thrive (Scott 2008). Indeed, actors’ acquisition and pursuit of legitimacy in their activities, and their valuation of these activities, are the tools of institutional work, where perceived legitimacy can initiate institutional change or maintenance. That is, as actors engage in processes to legitimize their activities and to describe their consonance with relevant rules, laws, norms, or cognitive frameworks, this consonance allows for the reshaping or maintenance of institutions, as norms and modes or working are changed or maintained by actors. Though it is individuals (or organizations) who engage in legitimizing work, this work extends beyond self-justification, and is an inherently social process that necessarily appeals to broader institutions, organizations, and social groups (Smith-Doerr 2005). By examining how entrepreneurial scientists seek legitimacy, as institutional workers, we suggest the ways in which these scientists can participate in the institutional change or maintenance of the academic biomedical research enterprise.

2. Methodology

This institutional work analysis of academic entrepreneurship in the biomedical sciences in Canada draws from twenty-four semi-structured qualitative interviews with Principal Investigators (PIs) holding grants through Canada’s publicly-funded health research program, the Canadian Institutes of Health Research (CIHR), under the funding theme of Biomedical Research (i.e. basic science, and not clinical or population health research). Each of the basic, biomedical researchers interviewed for this study was engaged in entrepreneurial activities, defined broadly as outward-facing activities to connect and engage with the private sector in their academic science. Specifically, they were engaged in both collaborations with private industry and the commercialization of their research (either through

the holding of patents or the initiation of spin-off companies). Interview participants were identified through their responses to a national survey of publicly-funded academic basic biomedical researchers in Canada, the results of which are published elsewhere (Miller et al. 2013, 2014). Researchers who met these criteria of academic entrepreneurship were contacted with an invitation to participate in this interview study, and participants were sampled for maximum variation in career stage and location across Canada. Participants were thus recruited by virtue of their status as publicly-funded academic scientists who had also participated in entrepreneurial activities (both commercialization activities and collaborations with industry), and not because of their organizational or scientific-field similarities. Academic entrepreneurs in this sample thus drew from diverse organizational settings and were conducting diverse types of basic biomedical research. As such, this study does not account for organizational differences or organizational constraints that may influence actors, nor does it look at differences among different types of scientists, but instead seeks to investigate how academic entrepreneurs across settings and across biomedical scientific areas understand, manage, and legitimize entrepreneurial science.

Respondents who agreed to participate in an interview were given a choice of modality, including face-to-face, telephone, or by Internet video-conferencing (e.g. Skype). Interviews lasted between thirty minutes and two hours, and were conducted between August 2011 and April 2012. All interviews were transcribed verbatim and uploaded to QSR NVivo qualitative data analysis software (v. 7) for coding and analysis. Interview transcripts were de-identified to maintain the confidentiality of participants. Data collection and analysis occurred iteratively, and interviews were conducted and modified as themes from these interviews emerged.

The approach to qualitative data collection, analysis, and interpretation drew from theories of constructivist grounded theory (Charmaz 2006). These theories centralize the study of action and examine how agents understand and make sense of their actions and social realities. Through interpretation, analyses render an interpretive portrayal of these agents and their organizational and institutional environments, rather than an exact picture of their realities. Using theories of institutional work, entrepreneurial scientists were understood conceptually as embedded agents in pursuing institutional legitimacy, and in interacting with diverse institutions to initiate institutional change or maintenance through their actions at the micro-level. Interview analyses thus drew from both grounded theory, in allowing themes to emerge from scientists’ experiences and interpretations of their engagements with entrepreneurial science, and theories of institutional work in locating scientists as institutionally embedded agents who interact with diverse institutions in shaping their research and institutional environments.

The interview guide asked participants to describe their entrepreneurial engagements (collaborations with industry and commercialization activities), their motivations for participating in these activities, and the management of their entrepreneurial pursuits in their academic laboratories. Scientists were also asked, at the end of the interviews, to reflect on the potential for conflicts of interest in entrepreneurial activities. Conflicts of interest were introduced not as a necessary situation that scientists were facing, as this approach would be constraining to open discussion, but instead as a critique launched externally by regulators or ethicists. By probing conflicts of interest in this way, interview participants were asked to reflect on conflicts of interest as a construct to be unpacked, rather than a necessary condition of entrepreneurial science. Focusing on accounts of motivations to participate in entrepreneurial activities and

understandings of conflicts of interest in this context, interviews were initially coded to descriptively group these responses by domain of value scientists granted to their entrepreneurial activities, as well as their engagements with the concept of conflicts of interest. Using theories of institutional work, entrepreneurial scientists' accounts of their motivations and their understandings of conflicts of interest were taken to be engagements with the institutions of academic and entrepreneurial science, aimed at the pursuit of the legitimacy of entrepreneurial science.

3. Results

First, we review the types of value that academic entrepreneurs indicate in their entrepreneurial activities. As indicated, we understand value both as valuations of entrepreneurial activities, including actors' motivations for pursuing them (e.g. why they should be pursued), and the outward facing social value that academic entrepreneurs perceive in these activities. Entrepreneurial scientists interviewed for this study claimed value in entrepreneurial activities in (1) contributing to scientific practices through financial and intellectual resources; (2) generating societal and economic impacts; and (3) generating clinical impacts and health benefits. Yet, scientists simultaneously claimed adherence to the importance of more traditional academic values, norms, and activities, such as disinterested science, academic freedom and autonomy, and the importance of curiosity-driven research. However, rather than taking these sets of claims to be contradictory instances, we argue that assertions of adherence to academic norms work together with assertions of benefit and value in entrepreneurial science to serve as legitimizing constructs. The institutional work examined here is largely normative and discursive, as entrepreneurial scientists draw from both academic and entrepreneurial institutions to begin to reshape the norms of academic science through the legitimization of entrepreneurial activities.

3.1 Valuing entrepreneurship for financial and intellectual resources

Interview participants described positive value in entrepreneurial activities for their capacity to contribute resources to scientific practices and to enhance scientific activities. Collaborations with industry, including conducting contract research and receiving research grants from industry, were valued both for their ability to enhance academic science by providing additional financial and material resources in the form of funds and equipment to academic science, as well as their ability to add enjoyment or intellectual resources to scientific practices.

In describing the value of entrepreneurial activities in generating financial outcomes, scientists described a poorly-funded research environment in Canada—specifically from Canada's federal health research funding agency, the CIHR—and thus proposed a necessity in additional entrepreneurial resources to fund the activities of their academic laboratories. Industry funds allowed them to take on high-risk projects or to engage in research projects that they otherwise would not be able to. The following account from a clinician scientist located in a hospital research institute highlights difficulties with securing public grant funding and the value of entrepreneurial activities as additional funding sources.

One of the main drivers of that is not just the commercialization, but to try to get more funding. One of the problems we have is, as researchers in general I think, is just the amount of funds from CIHR and other funding agencies. We never have enough money

to do anything like really well . . . The vast majority of people are struggling, and trying to cut corners, and the funders are getting good value for their money, but there's not enough money around. So if you want to do something that's exciting and a little bit more, it's always difficult. So, if you have an angle with industry, an industrial angle that you see might benefit a pharmaceutical company or some other company, many people will go to them for funding for one reason or another. [R1]

In the next excerpt, entrepreneurial activities are described as having relatively few costs but great benefits for academic science. According to this university professor, writing a business plan to acquire a large amount of money—one million dollars—was procedurally commensurate with writing an academic grant for much less:

You can build up labs with much better funding from the private [sector], and push your science along much quicker with much higher and better funding on a per year basis if you have private funding, and that was one thing. So that was very motivating because at some point we had the choice I think to either write another grant for \$100,000 a year, or write a business plan and get a million dollars per year, and so we went for number two, because we just thought it would be great, and it worked, right? And that was great too. [R18]

These scientists thus claimed that entrepreneurial activities could facilitate or enhance the science of their labs through providing necessary resources, without deleterious changes to the nature of their science or the types of activities in which they engaged. Entrepreneurial activities, in this context, were characterized as financially beneficial add-ons to academic laboratories that could better resource these laboratories to do better, more exciting science.

Alongside these accounts of the positive value of entrepreneurial activities in enhancing scientific practice through the provision of financial resources, scientists also claimed positive value in the enjoyment and intellectual resources that entrepreneurial pursuits could add to their scientific activities. They valued the scientific insights and intellectual capital that could be accessed through collaborations with industry, as well as the challenges and research directions provided by industrial partners. Academic entrepreneurs valued the possibility of research application or translation that they could achieve through research collaborations with industry. The following account from a molecular biology professor at a university research institute identifies value in industrial collaborators who can enhance academic research and who are conducting research in focused way:

So the interest in collaborating with companies is number one, you tap into this incredible knowledge base that you just don't get in your day-to-day interactions, or often you don't get from working with expert collaborators in academia. Industry collaborations give you this view into a group of people who are all working really hard on one particular problem, and so it's always a learning experience and an intense one in a field that I'm usually not that well versed in. [R13]

In these accounts, entrepreneurial scientists claimed that their entrepreneurial activities provided valuable extensions to academic science through scientific excitement and novel research directions, ultimately augmenting scientific practice.

3.2 Valuing entrepreneurship for societal and economic impacts

Beyond the value that scientists claimed in entrepreneurial activities for scientific practices, we next demonstrate the ways in which they

claimed normative value in entrepreneurial activities for their ability to generate downstream societal and economic impacts. Language of return on investment and the generation of impact from academic research were used to explain what was perceived as a new mission or mandate of academic science, in producing societal impact and directing academic research toward these ends. Interview participants commented on a shifting academic research environment toward increased obligations to produce societal value, jobs, and economic impacts from academic research. For example, this university-based professor located in a biomedical engineering department described a new model of academic science, where societal impact is part of the mission of academic science.

The old the model of universities as centres of higher learning, separate from the economy, separate from the rest of the community, I think are old models. I think modern universities are getting to be integrated into the community with downtown buildings, parts of universities downtown in cities, in supporting city planning, supporting commercialization and job activity. So I think the role of universities is changing and now they have to undertake this kind of partnership with the rest of the economy, and that means that conversion of public money support into economic activity. [R6]

In addition, the generation of societal impact in academic science was characterized as a specific obligation of publicly-funded researchers, and especially of health researchers in Canada. The following accounts from a university-based assistant professor and a hospital-based clinician scientist valued aspects of return on investment for Canadian citizens as necessary and beneficial outcomes of entrepreneurial pursuits, and indeed as obligations of academic researchers toward the public.

If you have something that could be of value- that's the whole reason why the government funds us in the first place- to do research to hopefully find things that are of value to Canadians... and so if we don't work with industry then you lose that in many cases. I think you lose the impact of the work, it doesn't get translated. [R12]

The public wants us to be generating jobs, high value information technology jobs here, and we're not going to do that if we don't start companies. [R2]

In these accounts, scientists claimed that beneficial societal and economic outcomes could be accrued from entrepreneurial activities, and spoke to an expanded mission of academic biomedical research in generating downstream impacts, related to research impact through translation and job creation. Rather than locating entrepreneurial science as a distinct resource, apart from but useful for academic activities, these accounts incorporated entrepreneurial, translational activities as necessary aspects of doing academic research in a new era.

3.3 Valuing entrepreneurship for clinical and health impacts

Connected to these rationales of downstream impact value for societal and economic benefit, but specific to the health research context, entrepreneurial activities were also valued for their ability to help patients and save lives, and to do so in a way that was superior to academic translation activities. For example, this university professor discussed how academic research translation mechanisms were insufficient to realize the health goals and imperatives of

biomedical research, and instead, the patenting and licensing of a technology was cast as guaranteeing patient benefit.

The basic motivation is that if you develop a prototype of something in the lab and it looks like it would be useful and helpful to a number of patients, if you don't [commercialize], it just remains a laboratory curiosity really, that may be the subject of a paper or two and then does nothing beyond that. If you patent it and license it and make arrangements to sell it ... then you can help thousands of people. [R14]

In the following account, this hospital-based clinician scientist positions achieving health goals and reaching patient populations as an ultimate goal for basic biomedical scientists. In doing so, they claimed that both academic entrepreneurship and the 'vested interests' of industry were necessary to push research toward these valued ends.

Ultimately what we'd like to do ... is getting something for people that's going to help them stay healthy and so on. The usual thing that we try to do is to translate the work, so it's these translations that are very difficult to do because of lack of money and you need someone to believe in you and in the idea to push it, you know, and someone with a vested interest. [R1]

In these accounts, the goals of patient benefit and cure, and the ways in which entrepreneurial activities might guarantee this, made it necessary to engage in entrepreneurial activities in order to create clinical impacts. As clinical impacts and patient benefit were inscribed into the purpose and mission of biomedical science, entrepreneurial activities were positioned as the mechanisms to achieve these impacts.

3.4 Asserting disinterested and unconflicted science

Though the previous accounts emphasized the proposed value of entrepreneurial arrangements for their societal, economic, and clinical impacts, this was not to the exclusion of basic or curiosity-driven research, which was identified as important to protect. In doing so, scientists challenged a potential overemphasis on the generation of impact in academic research. In the following account, this scientist questioned the effectiveness of governmental and funding initiatives that promote commercialization overall. They still maintained the importance of societal impact in academic research, including through commercialization, yet found basic science and serendipitous discovery to be the means to that end.

I believe that scientists have responsibilities to society, to do something that helps society, it's just that over the course of time we've learned that a lot of curiosity driven research is the right way to form that base. And then from that base, discoveries emerge that will have commercial value and practical value and biomedical value and everything else. So, in my own personal view, curiosity driven research is not a moral, ethical principle, it's simply a tried and true method of creating the knowledge base that's necessary to move forward. [R24]

Entrepreneurial scientists thus both claimed the importance of directing research toward societal applications and producing impact, and also serendipitous discovery and basic research as the source of innovation and potentially commercializable outcomes. They tended to resist organizational, governmental, and policy directives that might enforce the generation of impact as a requirement in academic biomedical research, and claimed the importance

of protecting basic science as a means of producing translational benefit.

These scientists also used their position as basic researchers to distance themselves, and the field of biomedical research as a whole, from the potential for conflicts of interest, when this possibility was proposed to them. Indeed, alongside the value proposed in clinical directedness and researcher interest in clinical applications and outcomes, academic entrepreneurs simultaneously distanced from the clinic in the context of proposed concerns about conflicts of interest, and maintained a position as basic, non-conflicted scientists. When discussing the concepts and management of conflict of interest, entrepreneurial scientists characterized conflict of interest situations as those faced by clinical scientists, or by researchers in close proximity to the clinic. They also distanced the field of upstream biomedical research as a whole from conflict of interest concerns, and in doing so avoided even the potential for encountering these situations. For this university-based neuroscience professor, distance from a clinical trial stage of research was used to dispel conflict of interest concerns.

I don't feel as a basic researcher that I have any conflict of interest at all in terms of the outcome of the study, right? ... So, it seems to me, you know, patently absurd that anyone would think that a guy like me is in a conflict of interest position in terms of the outcome of the study, right? And I don't feel in any way that the drug company cares one way or another whether the study succeeds or fails. If it succeeds, it's just one more of a long list of data points that would get them closer to making a go decision on a clinical trial, and then if it fails it's just one of a long list of experiments that would make them slightly less likely to make a go decision on a clinical trial. [R5]

Similarly in the following account, this engineering professor distinguishes their research from situations where individuals might benefit personally from their collaborations with industry.

I think there's many cases where [conflict of interest] is a very legitimate concern, a lot of the pharmaceutical research, deep concerns, where the researchers stand to benefit personally from these collaborations. In our case, the personal gain is very, very far from any of this and so there's a much, at least in the case that I've experienced so far, there's very few issues in terms of conflict of interest. [R22]

Here, distinctions were made between industry collaborations in the space of upstream biomedical research, where outcomes are characterized as more abstract, and in the space of clinical research, where outcomes are characterized as more visible or evident.

These contradictory justifications posed by academic entrepreneurs, in both claiming benefit in the pursuit of entrepreneurial activities to reach clinical populations and concurrent distancing from clinical settings in the face of conflict of interest concerns are most evidently displayed in the following account. This director of a research center, described basic biomedical research as having a health-centric and clinically-oriented mission. As a means of fulfilling this mission, collaborations with industry were valued as necessary mechanisms to resource and translate academic research to clinical settings.

If you work in biomedical research, where the work has a mission, which is eventually to improve health, then it's the rare academic lab that could actually get all the way to a patient without having a private sector partner somewhere along the way. You know, you don't have the capacity to do a large, expensive Phase

III trial, so therefore industry has its legitimate role in the continuum from a basic discovery to a product that is being sold as a drug or as a device, so it's fundamental. [R24]

However, when asked about the potential problem of conflicts of interest associated with entrepreneurial activities in the conduct of academic biomedical science, they distanced the field of basic biomedical research from this health-centric mission.

Now [conflict of interest is] much less of a problem in a very basic science supported protocol that is years and years and years away from any patients being involved or clinical decisions being made, because then the company's paying for some experiments, nobody has any idea where it's going to go, you're not asking a patient to try the drug or not try the drug. [R24]

This contradictory characterization of the appropriate role of academic biomedical researchers with respect to the clinic is illustrative but not unique to the ways in which academic researchers positioned themselves. Though scientists demonstrated an awareness of the potential for conflicts of interest when industrial or proprietary interests become involved in research, they decoupled these concerns from the conduct of upstream, basic biomedical science. Conflict of interest concerns associated with doing health or clinical research were strategically removed or obfuscated from the conduct of basic science, and instead scientists emphasized the uncertainty or nondirectionality involved in their scientific practices.

4. Discussion

Similar to findings in other settings (Baldini et al. 2007; Fini et al. 2009; Lam 2011), academic entrepreneurs in this study found intrinsic satisfaction and novel research directions in the activities of academic entrepreneurship. However, these scientists did not draw motivations from personal financial gains or career recognition or rewards, but instead drew more heavily from the constraints and the demands of research funding. In claiming the value added to scientific practices through entrepreneurial pursuits, the financial and intellectual resources of industrial collaborations and industry funds were valued for enhancing academic science through the provision of research resources and intellectual stimulation for scientists, usually related to pushing research in translational directions. These pursuits were considered to be minimally invasive activities that would generate great benefits for academic science. They were also cast as increasingly necessary pursuits in a poor funding environment, and as legitimate for their potential to enhance academic science in an environment that was described as scarce in resources, and where industrial research directions could augment academic science.

Claims about the generation of societal and economic impacts through entrepreneurial activities, however, diminished the divide between academic and entrepreneurial science. Through a claimed expanded mission of academic science in generating social and economic impacts, entrepreneurial activities were cast as the mechanism through which these impacts could be achieved. In these mission-oriented contexts, entrepreneurial scientists both claimed the value of entrepreneurial science itself, and also sought to legitimize entrepreneurship as an aspect of academic science, thereby merging these two diverse institutions. These claims about impact value in entrepreneurial activities characterized entrepreneurial science as a beneficial component of modern academic science, rather than a distinct set of activities.

Scientists' claims about clinical and health impacts as a result of entrepreneurial activities most clearly denote the ways in which entrepreneurial activities were valued as increasingly legitimate extensions of academic biomedical science, as academic entrepreneurs invoked promises of curing patients and saving lives. In these accounts, health impacts were used to justify and valorize entrepreneurial engagements (Lehoux et al. 2014), and scientists used the promisory discourses of medical advancement to legitimize their scientific activities (Hobson-West 2012), in this case, those of academic entrepreneurship. The practices and activities of academic entrepreneurship, among these scientists, were characterized as legitimate through their alignment with academic research activities, and the shared goal of downstream health impacts. Scientists in this study described, and indeed claimed to foresee and ensure, that benefits to patients could be achieved through entrepreneurial activities. Indeed, translation to the clinic was positioned as a fundamental aspect of doing basic biomedical science, and inscribed into the mission of academic biomedical research. As such, participation in entrepreneurial activities that required the pursuit of patents, the creation of spin-off companies, and collaborations with private industry were characterized as fundamental and necessary activities for basic biomedical researchers to engage in, with the intended ends of clinical impact.

Yet, alongside these claims about the generation of impact in entrepreneurial activities, scientists resisted directives that would force research in this direction, and spoke to the importance of basic research and serendipitous discovery. In doing so, they claimed to protect academic freedom and non-directed discovery while maintaining the value of impact and economic development as an aspect of academic research. Scientists thus espoused the value of directing science toward applied ends as a beneficial and mission-centric pursuit, yet also resisted the imposition of these applied ends and protected the value of serendipitous discovery. They claimed that entrepreneurial activities could produce societal impacts, yet maintained simultaneous adherence to the importance of basic, 'blue skies' research.

Entrepreneurial scientists' discussions about the proposed problem of conflicts of interest also caused them to distance themselves from clinical impacts and claim a role as disinterested scientists. Conflicts of interest became cast as an irrelevant concern for these scientists through their claimed distance from patient populations, both for individual scientists, and for the field of basic biomedical science as a whole. In order to justify and legitimize entrepreneurial activities, these scientists thus distanced from the clinic in the face of proposed harms, and denied the possibility that entrepreneurial activities would link the worlds of basic biomedical science and clinical impact. This strategy formed part of a legitimizing discourse for entrepreneurial scientists, where entrepreneurial activities were valued for their ability to achieve patient benefit, yet not be subject to the concerns of clinical research. Through deflecting harms and emphasizing the downstream potential benefits of entrepreneurial science, these pursuits were cast as legitimate, aligned with the mission of academic science, and free from potential harms. Through the deflection of conflicts of interest to clinical spaces, scientists created legitimacy in their own pursuits (Brosnan and Cribb 2014), and purposively decoupled (Smith-Doerr and Vardi 2014) the potential for downstream impacts of their activities from their scientific practices, related to bias in the results of research and potential harms to patients and the public.

4.1 Institutional change-through-maintenance

The entrepreneurial scientists in this study engaged in a seemingly contradictory set of positions, both claiming the benefits of entrepreneurial activities for academic science, and also claiming to ensure against their harms and protect academic norms and values. While they claimed positive normative value in entrepreneurial activities for academic scientific practice and downstream impact, they simultaneously claimed to attend to the harms of industrial overtake of academic research programs, an overemphasis on commercially directed research, and the potential for conflicts of interest. We argue that academic entrepreneurs appeal to the maintenance of academic norms and practices strategically, in order to legitimize the value of entrepreneurial science. It is through this attendance to academic norms and institutions that entrepreneurial activities are legitimized as academically-aligned and beneficial, and through which scientists claim that they can accrue the described benefits of entrepreneurial science while simultaneously protecting the integrity of academic science through attention to academic institutions. Academic norms, values, or logics thus serve as tools of legitimacy in entrepreneurial scientists' institutional work processes, and serve to legitimize entrepreneurial activities as academically aligned.

Using the tools of academic legitimacy in their conduct of institutional work, the entrepreneurial scientists in this study legitimized entrepreneurial pursuits through claims that these could enhance the activities of academic science, for example by providing research funding and support and by facing academic research toward societal needs. Through a distancing and deflecting of the potential for the harmful effects of entrepreneurial science on academic research, and the maintenance of a position as disinterested basic scientists, they proposed an ability to protect academic freedom, autonomy, basic research, serendipitous discovery, and scientific disinterestedness alongside entrepreneurial initiatives. Through their simultaneous claims to adhere to the institutions of academic science and to avoid conflicts of interest, they claim new zones of legitimate scientific conduct where entrepreneurial activities are valued and academic norms can be maintained. Engaging in ethical boundary-work, they use a position of disinterestedness and appeals to their maintenance of academic positions to legitimize entrepreneurial initiatives as free of potential threats to academic scientific practice.

Jain et al.'s (2009) characterization of the 'hybrid role identity' taken on by academic entrepreneurs examines how academic scientists who undertake entrepreneurial activities invoke rationales that are congruent with their academic role identities. They accomplish this either by delegating their entrepreneurial tasks to other actors or by buffering their entrepreneurial activities from their academic responsibilities (Jain et al. 2009). While the scientists in our study demonstrated evidence of both delegating and buffering, and doing so strategically to avoid the problem of conflict of interest, situating entrepreneurial scientists as institutional workers extends beyond scientists' individual role identities and examines how the actions and espoused rationales of entrepreneurial scientists can begin to interact with the institutions of academic science. As academic entrepreneurs claim an alignment, and an ability to manage academic and entrepreneurial pursuits, they also engage in a legitimization process that makes entrepreneurial activities institutionally aligned with academic activities, and thereby obfuscates the potential for the outcomes of conflict of interest that may be connected to these activities.

We argue that entrepreneurial scientists in this study are engaging in an institutional work process of *change-through-maintenance*,

where they interact with appeals to the maintenance of institutions of academic science in order to reshape new values and modes of conducting academic biomedical research. Their normative claims about the value of academic entrepreneurship introduce entrepreneurial activities as legitimate scientific practices through an adherence to, and extension of, academic norms. As entrepreneurial scientists generate new domains of legitimate academic scientific practice in entrepreneurial activities through claims about the normative value of these activities, their strategic claims to adhere to the maintenance of academic norms and institutions serve as legitimizing forces. These claims of legitimacy both work to protect actors' own engagements in entrepreneurial activities, which may be controversial, and promote the benefits of these activities as normatively valuable for academic researchers at large.

As institutional work examines the negotiations of institutions on the ground, as actors create, maintain, and disrupt institutions (Lawrence et al. 2009), this study provides an empirical investigation of these initiatives at the normative level, in an institutional environment of divergence, heterogeneity, and uncertainty. By studying micro-level processes that occur in the normative claims of academic entrepreneurs, this study examines institutional change as a dynamic, contested, and ongoing process that is often without a clear direction (Lawrence et al. 2011). These findings augment the literature on academic entrepreneurship by examining how the logics of academic science and entrepreneurship can reinforce each other, and focusing on the activities of institutionally embedded agents—academic entrepreneurs—in their pursuit of institutional work to legitimize these activities. As well, this study advances scholarship on institutional work by introducing the process of change-through-maintenance, and examining how institutions can begin to change institutions through maintenance claims and through claims that legitimize new pursuits as aligned with existing ones.

This examination of institutional change-through-maintenance in the institutions of academic and entrepreneurial science also has implications for science and health research policy and the regulation of academic–industry collaborations or financial and commercial interests in research. We have shown how academic scientists, holding competitive funding grants from Canada's federal health research funding body, who also collaborate with industry and have pursued research commercialization activities may be engaged in processes of reshaping academic science through claims that entrepreneurial science is aligned, beneficial, and free from potential harms. The policy and research ethics concern and implication lies here in the ways in which these activities of change-through-maintenance may obscure the ways in which market-driven interests in publicly-funded academic science may override the public and scientific interests of research, in favor of industrial or profit-driven science. As these processes unfold, there is a need for attention and vigilance to the potential negative outcomes of entrepreneurial activities in academic science.

Given the existence of concerns about conflicts of interest in health research, and evidence that those who face these conflicts tend not to recognize them, this demonstration of the legitimization of entrepreneurial activities through claims of maintenance of the norms of academic science raises concerns that potentially harmful activities may be unquestioningly legitimized as harmless and academically-aligned pursuits. The findings of this study indicate that entrepreneurial scientists believe that they themselves can be the arbiters of balancing the benefits of entrepreneurial science, while controlling and avoiding relevant harms. While entrepreneurial

scientists claim that the practices and norms of academic science can exist alongside entrepreneurial activities, and that curiosity-driven and open-ended research can exist alongside entrepreneurial and directed research, the potential for an entrepreneurial or industrial ethos to overtake academic science is an increasingly legitimate threat (Vallas and Kleinman 2007).

Though entrepreneurial scientists tended to deny and offload conflict of interest concerns, conflicts of interest are inherently embedded into their entrepreneurial practices through concurrent commitments to commercial, industrial, and academic science (Emanuel 2007; Lemmens and Luther 2008; Porter 1992). As entrepreneurial biomedical scientists increasingly orient toward patients and the clinic, and use these projections to legitimize entrepreneurial activities as academic science, the harmful outcomes of conflict of interest that can threaten patients and the public cannot be forgotten or obfuscated. There is thus a research policy need—both at the national and organizational level—to scrutinize and monitor industrial arrangements among academic scientists and attend to their potential detriments.

5. Conclusion

The findings of this study suggest that entrepreneurial scientists initiate an institutional work process of change-through-maintenance, where appeals to the alignment and maintenance of academic norms and practices serve to legitimize entrepreneurial activities, and where entrepreneurial scientists claim that these two institutions can co-exist. As entrepreneurial scientists actively create legitimacy in academic entrepreneurship and deflect concerns about conflicts of interest, this study also assesses how the potential for conflicts of interest shape the legitimacy of entrepreneurial science in the context of biomedicine, where legitimacy can be gained through a distancing from this proposed set of harms. Specifically, we have demonstrated that academic entrepreneurs utilize the institutions of academic science to legitimize their entrepreneurial pursuits, and in so doing, minimize and deflect the potential for conflicts of interest to arise from dual commitments to academic science and industrial interests.

As well, this study brings forward the importance of health claims in scientists' normative valuations of their entrepreneurial pursuits. Specifically, we have shown that biomedical scientists utilize claims about the health impacts of their research to legitimize their entrepreneurial arrangements, thereby bringing applied health-related impacts into basic biomedical science to legitimize entrepreneurial initiatives in orienting research toward the clinic. As health impacts are included into the mission of basic biomedical research, entrepreneurial scientists legitimize entrepreneurial activities by claiming that these ensure the translation of biomedical research to clinical applications.

In addition, this study has demonstrated how ethical concerns, especially those about conflicts of interest, can shape laboratory practices (Brosnan et al. 2013; Hobson-West 2012; Wainwright et al. 2006). Drawing on these theories of 'ethical boundary-work', we show that when confronted with concerns about conflict of interest, entrepreneurial scientists draw lines around 'conflicted' and 'unconflicted' science in order to enable their entrepreneurial activities. By claiming that their entrepreneurial pursuits are distinct from pursuits that might cause conflicts of interest, they enable their own entrepreneurial pursuits to proceed as 'unconflicted', thereby legitimizing these initiatives. We also demonstrate a precarious

relationship between the health claims made by scientists and their stance on conflicts of interest, where entrepreneurial scientists both value and forecast the health implications of their research, and also distance from clinical settings in the context of conflict of interest concerns. Taken together, the ethical boundary-work of distancing from the clinic in response to conflict of interest concerns, and the forecasting toward the clinic to legitimize or necessitate entrepreneurial activities, form part of an institutional work process of institutional change through claims about the maintenance of academic, non-conflicted science.

These processes of institutional change-through-maintenance and the obfuscation of the potential for conflict of interest to enable this have implications for the governance of entrepreneurial science in academic settings, as entrepreneurial activities become legitimized by academic entrepreneurs, while their harms are diminished. Given these ongoing institutional processes, both launched top-down from policy and funding initiatives and bottom-up by the scientists that participate in them, the findings of this study call for a need to scrutinize scientists' engagements with entrepreneurial science. This requires not just the actions of scientists themselves in managing the boundaries of academic and entrepreneurial science, but also support from academic structures and funding bodies in prioritizing academic science (Vestergaard 2007).

At the organizational level, universities and academic research funders have made significant strides toward developing comprehensive conflict of interest policies, and have erected policies and structures that both enable academic entrepreneurship and those that restrict it in some regard. This study demonstrates that entrepreneurial scientists themselves can shape organizational practices through the legitimization of entrepreneurial activities as academically aligned. As these entrepreneurial processes become legitimized by scientists, there may be a tendency for academic structures and organizations to downplay the potential for conflicts of interest and other forms of bias to enter scientific processes. We thus use our analysis of change-through-maintenance in the institutions of academic science as a call to recognize the potential for conflict of interest and bias in entrepreneurial activities, and call for university and funding body policies to account for these in policies and strategies moving forward.

Yet, this study also confirms that the term 'conflict of interest' may restrict discussion and identification of potential issues in the management of academic entrepreneurship. As conflicts of interest tend to be understood pejoratively, and are often cognitively linked to situations of research misconduct (Williams-Jones 2011), there may be a need to reconsider the language in which discussions about the potential harms of entrepreneurial activities are held. The concept of a 'conflict of interest' did not resonate for the scientists in this study, and these findings suggest that new terms or ways of thinking about the potential for the import of bias into academic science through private sector, industrial interests may be needed. This study demonstrates that the construct of conflict of interest may halt discussions of the potential implications of entrepreneurial science, calling for terms or definitions that hold more meaning for academic scientists.

Future research might examine the clinical translation impacts of academic entrepreneurship that were highlighted in this study. Entrepreneurial scientists interviewed for this study asserted certainty in the ability of their research to generate patient benefit and valued entrepreneurial activities to this end. These pathways of clinical benefit require further investigation as scientists tended to ignore uncertainties related to market and clinical uptake of new

technologies. Indeed, the findings of this study necessitate an ongoing examination of academic entrepreneurs in the biomedical sciences in order to track how new institutions of academic science come to dominance and how academic scientists come to legitimize or resist these initiatives.

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