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# How Pharmaceutical Industry Employees Manage Competing Moral Commitments in the Face of Public Criticism

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## Abstract

The pharmaceutical industry has been criticised for pervasive misconduct. These concerns have generally resulted in increasing regulation. While such regulation is no doubt necessary, it tends to assume that everyone working for pharmaceutical companies is equally motivated by commerce, without much understanding of the specific views and experiences of those who work in different parts of the industry. In order to gain a more nuanced picture of the work that goes on in the “medical affairs” departments of pharmaceutical companies, we conducted 15 semi-structured interviews with professionals working in medical departments of companies in Sydney, Australia. We show that this group of pharmaceutical professionals are committed to their responsibilities both to patients, research participants, and the public and to their companies. Despite the discrepancies between these commitments, our participants did not express much cognitive dissonance, and this appeared to stem from their use of two dialectically related strategies, one of which embraces commerce and the other of which resists the commercial imperative. We interpret these findings through the lens of institutional theory and consider their implications for pharmaceutical ethics and governance.

**Keywords:** Qualitative research; Social values; Pharmaceutical industry; Pharmaceutical ethics

## Background and Rationale

In recent years, the pharmaceutical industry has come under fire for what is perceived to be pervasive industry misconduct worldwide. Among other things, the industry has been criticized for developing medicines that are likely to be commercially successful even if these do not address genuine unmet needs; carrying out research without due regard for the well-being of research participants; distorting the design and interpretation of research in order to produce more positive findings; withholding negative results from publication; overstating the costs involved in research and development in order to overprice medicines;

misusing intellectual property laws; and engaging in ethically dubious marketing practices (see Kesselheim, Mello, and Studdert 2011; Komesaroff and Kerridge 2002; Lexchin et al. 2003; Glynn and Lounsbury 2005; Moynihan, Heath, and Henry 2002; Trouiller et al. 2002; Wager and Herxheimer 2003; Wazana 2000; Elliot 2010; Angell 2004).

These concerns have resulted in increasing regulation of the pharmaceutical industry, in the form of, for example, rules about the conduct of clinical research (e.g., the expectation that clinical trials will be registered prior to carrying them out [Califf et al. 2012]), marketing practices (e.g., most countries ban direct-to-consumer advertising of prescription pharmaceuticals [Mackenzie et al. 2007] and “off-label” marketing of drugs for indications that have not received regulatory approval [Tabarrok 2009]), and drug pricing and intellectual property (Blind 2012). There are also evermore demanding rules governing industry engagement with academic researchers and clinicians that limit the kinds of allowable interactions and demand disclosure of such interactions (DeMartino 2012).

While there is little doubt that the industry as a whole has engaged in each of the above forms of misconduct, and that regulation of the industry is essential, the heterogeneity of the industry and its actors is not often emphasised. Importantly, many employees in the medical and scientific departments of pharmaceutical companies have clinical and scientific backgrounds, in contrast to those in sales and marketing departments who usually have commercial backgrounds. While those in the medical and scientific departments are not necessarily the most powerful groups in pharmaceutical companies, they do have significant control over the conduct of basic research, clinical trials, applications for registration and subsidisation, medical information, and (albeit to a lesser extent) sales and marketing strategies.

Yet, these groups are often neglected in discussions of the pharmaceutical industry. Little is known about what motivates individuals in these pharmaceutical departments and, more specifically, how they cope with the potential tension between their commitments to adhere to scientific or medical norms and their commitments to advance the commercial interests of their companies. We do not know, for example, whether one set of commitments becomes dominant or whether both sets of commitments are viewed as equally important. And we do not know how competing commitments are conceptualized and negotiated in the course of their everyday work.

This is an important lacuna because, without a nuanced understanding of the workings of all aspects of the pharmaceutical industry, the discourse around the industry will remain impoverished, and we might miss important insights into how we can prevent and respond to industry misconduct. We therefore propose that a fruitful avenue for investigation is to understand what drives the behaviour of those who work in the “medical affairs” departments of pharmaceutical companies, to determine where their commitments lie and how they reason about their work in the face of potentially competing commitments. By understanding how these industry employees actually perceive and respond to their work, we might be in a better position to engage with them and regulate their activities.

Qualitative research is particularly suitable for this kind of analysis. To date, however, qualitative research has not shed much light on the values that drive industry employees. Instead, qualitative studies of the pharmaceutical industry have focused on industry employees’ views about corporate social responsibility in general (Zaharia and Ghenghea [Mladin] 2011; Lee and Kohler 2010) and specific aspects of pharmaceutical strategy and

policy such as facilitating and financing innovation (Biedenbach 2011), responding to new scientific paradigms (Dingel et al. 2012), conducting strategic clinical trials (Eisenstein et al. 2008), engaging with consumers (Hemminki, Toiviainen, and Vuorenkoski 2010), protecting intellectual property (Horikawa, Tsubouchi, and Kawakami 2009), regulating industry activities (Laeque et al. 2006), contending with globalisation (Wertheimer and Norris 2009), and facilitating good clinical practice (Wang et al. 2010).

A few exceptions are studies that have been conducted by Emily Martin and Steven Shapin. Martin interviewed people involved in pharmaceutical sales and marketing and concluded that, despite increasingly ruthless profit-seeking on the part of their corporations, contemporary pharmaceutical employees can still achieve a kind of moral microclimate in which to carry out their work (Martin 2006) and that they do so by “find(ing) ways of seeing their work as worthy according to old and enduring American ideas about virtue: pursuing a kind of ‘health altruism’ in which science is harnessed to produce devices that can improve health” (Martin 2006, 158). Shapin interviewed scientists who conduct their research in biotechnology companies rather than in academic laboratories. He found that while these researchers were proudly committed to their companies, they also emphasised the importance of continuing to engage in community service through teaching and of sharing results through open publication. Working for biotechnology companies was not necessarily seen to stand in the way of these more altruistic goals (Shapin 2008).

While these studies are helpful in demonstrating that industry employees are committed not only to their companies but also to the goals and methods of publicly funded science and medicine, they do not tell us to what extent, and in what ways, these potentially competing commitments are managed by those who work in medical departments of pharmaceutical companies in the face of sometimes intense public and professional condemnation.

In this article we report the results of a qualitative study of the values of academic scientists, doctors, and pharmacists who have left work in their original professions to work in the medical affairs departments of pharmaceutical companies. Our research questions were:

- 1) What evidence is there that people working in medical affairs departments of pharmaceutical companies exhibit a commitment to the commercial goals of their companies as well as to their social responsibilities to research participants, patients, and the general public?
- 2) If they exhibit multiple commitments, how do they manage potential conflicts arising from potentially incompatible commitments?

### **Theoretical Framework**

To assist us in this task, we drew on institutional theory (Scott 2008). A central premise in institutional theory is that the norms, beliefs, and rules in the relevant institutional environment play a key role in shaping behaviors in an organizational field. Scott and colleagues define the organizational field as the community of actors that “partake of a common meaning system and whose participants interact more frequently and fatefully with one another than with actors outside the field” (Scott et al. 2000, 13). Actors can be individuals, informal groups, organizations, professional groups, government agencies, and other actors. With this in mind, the pharmaceutical companies in our study could be viewed

as part of the organizational field of “drug development,” which would also consist of universities, regulatory agencies, hospitals, and so on.

As Scott and colleagues note, a distinctive characterization of an organizational field is its “common meaning system” or “institutional logic” that reflects the appropriate norms, organizing principles, and practice guidelines that constrain and empower social behavior of actors in the field (Scott 2008). However, because an institutional logic is both created (produced) and enacted (reproduced) by the actors themselves—who bring different interests, resources, and power to a field—an assumption of consensus or uniformity does not reflect reality.

Empirical studies have documented that fields are often the site of overt conflict and competition among various actors (D’Aunno, Sutton, and Price 1991; DiMaggio 1991; Scott et al. 2000; Suddaby and Greenwood 2005; Thornton 2004); other studies have demonstrated the potential for multiple logics to coexist within the same field (Hoffman 1999; Reay 2005; Reay and Hinings 2009; Goodrick and Reay 2011). Yet other studies suggest that field participants may interact over time to form a new hybrid of two previous, distinct logics (Glynn and Lounsbury 2005; Montgomery and Oliver 2009).

In keeping with the recognition that logics often coexist or hybridize, researchers have become increasingly interested in how field actors are able to navigate across two or more predominant institutional logics, and they have described a number of strategies for doing so.

One strategy is the process of decoupling, whereby actors reject elements of an undesirable logic that may be gaining influence, but do so under the radar so that their rejection is not obvious (Kitchener 2002; Pache and Santos 2011). Another strategy is that of pragmatic collaboration, which is invoked when it is in the interests of subgroups within the same field to work together so as to accomplish particular tasks, but the actors wish to do so without necessarily subscribing to one another’s logics (Reay and Hinings 2009). A third strategy entails enacting a part, but not the whole, of an alternative logic. This strategy is possible because, rather than being holistic, logics consist of decomposable parts that can be applied selectively. A group might choose to embrace only those elements from a new logic that fit with existing beliefs and practices (Meyer and Hammerschmid 2006; Nelson 2005), or they might change certain aspects of their own beliefs and identities to fit with more acceptable aspects of a new logic.

In summary, there is substantial evidence of the strategies that field actors engage in when confronted with multiple logics (i.e., variations of the common meaning system) within an organizational field. We point out that we did not conduct the study with this theory of institutional logics in mind. Rather, we found evidence in our emergent results of participants negotiating competing commitments, and we used institutional theory to help us with the organization and interpretation of our findings.

### **Research Setting and Methods**

We conducted 15 face-to-face interviews with pharmaceutical professionals working in medical and drug development departments (usually referred to as medical affairs departments) of nine pharmaceutical companies in Sydney, Australia. In Australia, almost all pharmaceutical companies are local subsidiaries of global companies. Our participants

represented most of the major companies that have an Australian presence, as well as one manufacturer of generic medicines.

We used a purposive sampling procedure to include participants from as many different companies as possible; from a variety of (non-commercial) professional backgrounds—particularly academic research, clinical medicine, and pharmacy—and with a variety of pharmaceutical company roles, including medical director, clinical research manager, regulatory affairs manager, and pricing and reimbursement manager; several participants currently or had previously held more than one of these positions (See Table 1).

Interviewees were identified first through organizational websites and the professional contacts of the research team and then via snowball sampling from the initial group. Sixteen people were approached in total and one declined to be interviewed.

Semi-structured interviews were conducted by the first author and lasted approximately one and a half hours each. Participants were first asked to describe, in their own words, their decision to move out of science or clinical practice and into industry as well as their experiences of making the transition. They were asked how they learned to fulfil their new roles and responsibilities and about the influence of any role models. They were asked to describe people they admired and people of whom they disapproved and to discuss those aspects of their work they found most and least rewarding. Finally, they were asked for their opinions on issues surrounding drug development, such as the globalization of clinical research, the current regulatory and economic environment, and relationships between industry and academia. Through this loosely structured format, participants were able to define and discuss their careers and working lives as they wished. Interviews were recorded (with interviewees' permission) and transcribed verbatim. Names were replaced by numerical designations.

We drew both on Morse's outline of the cognitive basis of qualitative research (Morse 1994) and on Charmaz's outline of data analysis in grounded theory (Charmaz 2006). This procedure involved initial coding via line-by-line analysis and gerunding to encode action or process, synthesizing codes into categories until no new codes could be developed from the data, focused coding using these categories, and abstracting into analytic categories. A coding tree was generated. Throughout the data analysis, a process of constant comparison was employed. Existing codes, categories, and concepts were refined, enriched, and reorganized as new codes; and categories and concepts were developed or as similarities and differences were recognized. Enough material was analysed to ensure that categories were saturated and all analytic categories were fully described and well understood. Thematic saturation was reached after approximately 10 interviews.

Importantly, we did not enter into the research process with the expectation that "negotiating competing commitments" would be a significant finding. This only emerged after we had analysed the interviews and the categories and concepts were developed from the data.

The study was approved by the university's research ethics committee. All participants signed consent forms and agreed to speak from their own (rather than their company's) perspective.

## Findings

### Evidence of Competing Commitments

We found strong evidence that our participants recognized and embraced two co-existing commitments: a commitment to the commercial interests of their companies and a broader commitment to patients, research participants, and society in general. We describe each in turn.

#### *Evidence of a Commitment to Commercial Interests.*

Our participants recognized and supported the commercial interests of their companies and emphasized the importance of investing wisely in the drug development process and generating brand awareness.

**P1:** We're a pharmaceutical company, and it's essential to make a healthy profit.

**P3:** At the end of the day, we're not a philanthropic organization. And I'm quite happy to say that. I know my part of it, and how those drugs were going to get on the market, and that's going to be beneficial, but they do cost money. ... And then do we make a profit? Yes, we do, we're a business.

**P4:** One of the key things is there's no point doing anything R&D if there's no registered product out there at the end of the day that's going to make the return on investment.

#### *Evidence of a Sense of Social Responsibility*

While our participants were clearly committed to their companies and their industry, they also demonstrated a strong commitment to the goals of science and medicine (i.e., a sense of responsibility to patients, research participants, and society beyond the confines of their companies). With respect to their reasons for engaging in this kind of work, all participants said that they were committed first and foremost to producing useful, safe, and affordable medicines for the general public.

**P3:** I believe in the principle of what we are doing, that we are proving that drugs are or are not safe and efficacious.

**P11:** I'm working on ... cancer ... so I am making a difference to patients' lives with new molecules like that. So you can get enjoyment from that aspect. And [my company] does have good products, they do have good molecules.

It was important to our participants not only to produce useful medicines, but also to make sure that they were safe to use and marketed and prescribed appropriately.

**P12:** One of the quotes I like to tell people is, I talked to a marketing person once and I said, “Well, where do you see your market for this product?” And he said, “Everyone with a mouth.” ... They were half joking, but it’s understanding that we are working with products that aren’t fast-moving consumables, and decisions are made on behalf of people that aren’t really capable of making the decision on their own, and the learned intermediary, whoever they are—doctor, pharmacist, nurse, and the industry—you have got to help them make wise decisions about their medicine.

A sense of social responsibility also played out in our participants’ relationships with a variety of external stakeholders. They saw it as their responsibility to support academic researchers, to consider national resources, and to have a global perspective on the effects of Australian drug development.

**P15:** One of the propositions that I was putting forward to government at all times is that a lot of the things that will facilitate industry-sponsored trials will absolutely help facilitate academic research. And in fact ... I’m more than happy ... to be pointing to things that are inhibiting academic research as well, because we support academic research in other ways.

**P9:** As a taxpayer I’m happy to see the government get value for money, as long as they don’t become pennywise and pound foolish.

**P13:** My feeling was that we, Australia, owe it to our cousins in Asia, for example, to bear them in mind when we are making our own decisions or when we develop our own processes, because what’s good for Australia might have these ripples elsewhere.

#### Managing Competing Commitments.

Interestingly, our participants did not express much cognitive dissonance or discomfort in the face of these potentially competing commitments—they moved freely in their talk from one set of commitments to the other. And while they acknowledged that the industry had a bad reputation, they almost always denied that this affected them emotionally or made them doubt their career choice. At most, they found such criticism “annoying,” “disappointing,” or “surprising.”

**P13:** What I find irritating is not so much working here, because we’re all in the same team here, what I do find irritating is that people who I feel are my peers and

colleagues in academia, who should know better, look down on us, for no good reason actually, or at least for reasons which are out of date. That annoys me.

**P12:** It was a bit of surprise really, because at the time [of joining the industry] I was on an editorial board of one of the pharmacy journals, and as soon as I joined industry they threw me off, and I thought, “That’s judging me for what I do, rather than what I am.”

Their ability to avoid cognitive dissonance appeared to stem from a number of strategies that they had for navigating across the demands associated with the two sets of commitments.

These strategies can be conceptualised as falling into two groups: First, there were strategies aimed at *embracing* commercial work, by reframing it so that it was more like scientific or medical work teleologically (in terms of its goals), technically (in terms of its methods), or morally (in terms of associated virtues). Second, there were strategies aimed at *resisting* being overwhelmed by the commercial imperative, by maintaining a scientific or clinical identity and by invoking personal ethics and/or organisational and professional regulation. Importantly, participants appeared to move freely between these strategies, suggesting that they are related dialectically, as illustrated in **Figure 1**.

Strategy 1: Embracing Commercial Commitments by Reframing Them as Being Like Science or Medicine

#### *Finding Common Goals*

Several participants emphasized the commonality in the goals and outcomes of the commercial and scientific-medical worlds. Medicine and industry were both seen not only to be interested in making money but also as being committed to improving patients’ lives.

**P2:** I liked the philosophy of the company in terms of being very open ... and putting always the patient first. ... So patient’s health, ensuring that’s at the forefront, but finding the sweet spot where you can make a buck, and do it ethically with the patient at the forefront. I like that approach. ... I think as you become more and more senior in the medical practice, you start realizing that actually we’re both here for the same purpose, doctors are in it to make a buck, pharmacy companies are in it to make a buck, and they both ultimately succeed when patients’ health is improved.

**P15:** So if they use [the medicine] right—the right patient, the right time—they get much better outcomes and they continue to use it. Doctors have used medications and [said] “won’t touch that again because I had a patient nearly die.” So you want to make sure those things don’t happen, because otherwise it’s bad for business and it’s bad for patients. But it’s bad for both.



### *Finding Common Methods*

Like science, industry work was seen to be “academic” and, like clinical practice, the industry was seen to be committed to following “best practice” guidelines.

**P6:** We tend to take a fairly academic approach to the work we do here anyway, so it’s not dissimilar [to academia]. In a case where you’re teaching ... you’re trying to ... teach up-to-date economic evaluations, methodology, both theory and practical. Whereas here what we do is we apply that ... so it’s no different. Like in medicine, would you go by the best practice guidelines to treat schizophrenia? The answer would be yes. And same with what we do: There are guidelines that are both developed by industry and government around “this is the best way to do an economic evaluation.” ... So it’s exactly the same.

**P1:** In the philosophy of science ... we set forward hypotheses and then we progress by rejecting hypotheses that we put to the test. My observation within industry is that that actually works very well. And the classic example would be a drug that might be in the early stages of development that shows poor efficacy or maybe potential adverse effects—that drug is stopped in its development and other projects are then brought forward instead. And that’s classic “rejection of the hypothesis” in science.

### *Finding Common Virtue Opportunities*

A third strategy we observed was that of finding opportunities to demonstrate virtue when working toward both commercial commitments and commitments to patients, research participants, and the general public. When talking about their commitment to patients and the general public, our participants discussed being compassionate and committed to others’ well-being. This concern for patients and the general public, in turn, demanded caution and protectiveness in the way that clinical trials were conducted and products were assessed for safety.

**P1:** We’re a pharmaceutical company, and it’s essential to make a healthy profit ... but I would use the word compassion. We do need to be compassionate in what we do.

**P9:** So most companies are ethical and professional, they’re not going to bring a product to market that’s harmful to the public.

In terms of their work orientation, our participants emphasized the importance of having scientific or medical knowledge and skills and enacting the classically “scientific” virtues of *objectivity* and *openness*.

**P2:** People want to know that [the] advice that they're getting is non-biased and straight down the line, so there's a lot more disclosure, which is good.

**P14:** When we collaborate with an institution, we have a [company] code on fireable offenses; we are not allowed to conduct research unless the researchers are free to publish.

While these claims could be interpreted cynically, with enactment or statement of virtues being seen simply as ways of maintaining a good image, we have no reason to believe that our participants were being disingenuous and, even if they were, it is still significant that they attempted to *demonstrate* publicly oriented virtues.

Interestingly, our participants' talk was equally virtue-rich when they were discussing their approach to their commercial commitments. Loyalty to shareholders was described with pride, as was being a team player within the company.

**P14:** We get funds from shareholders and shareholders allocate those funds. ... We must justify a commercial return commensurate with the rest of our industry, with our past performance, and with other industries as well.

**P8:** You have to participate in many teams and a lot of them with fairly robust discussion on "I think it should be developed like this," "no, I think it should be developed like this." You know what I mean. And you can end up with quite a robust scientific discussion, and there's no right and wrong, this person's process is quite okay, but in the end you have to make a decision.

It was seen to be important to be tenacious and personally committed to one's product, while at the same time being sufficiently tough to tolerate knock-backs and flexible enough to change one's strategy when needed.

**P3:** [discussing clinical research] We're out there, we're passionate about the drug. ... There's a sense of ownership about the product that is developed. ... (But) It's quite challenging, they get a lot of knock-backs. ... You need quite a lot of tenacity, patience, perseverance, you've got to have a little bit of a thick skin.

**P6:** [discussing regulatory submissions] It might take two or three meetings of the PBAC [Pharmaceutical Benefits Advisory Committee]. ... So over a period of time you change the strategy, might be niched as opposed to a broader listing ... you might change your strategy.

Caution and thoroughness were other commercially relevant virtues, aimed at living up to expectations and preventing criticism of the company from outside.

**P6:** [discussing economic applications] They get hold of the data, they can review the data, it's embarrassing if you make mistakes, it's embarrassing, and it can go very much against you if you cause delays, if you actually leave out information.

## Strategy 2: Resisting the Commercial Imperative

Our participants described three tactics that appeared to be part of an overall strategy for maintaining some separation and distinction from those engaged in purely commercial pursuits, without similar professional backgrounds.

### *Maintaining an Academic–Clinical Professional Identity While in Industry*

Several of our participants emphasized the importance of preserving their “pre-corporate” identities, in a way that enabled them not only to see themselves as scientists, doctors, or pharmacists but also to feel seen and valued by others as having these identities.

**P12:** If I couldn't [preserve my identity as a clinician] I'd leave [the company]. Because that's the ultimate, that's the bottom line. I mean, I consider ... that your primary role as the health professional working in the pharmaceutical industry is as a patient champion, you are always to take the role of the patient, to take the rough edges off the commercial imperative of the company. And I've been lucky enough to work with senior people that are running the company that respect that, and value it, and like to have it. And you are coming from a different perspective all the time.

**P15:** Yeah, I do [still see myself as a pharmacist], although it's becoming more tenuous, my ability to point to that. Yeah, I think I'll always consider myself as a pharmacist, where I started from.

For some, this entailed keeping a foot in both worlds.

**P6:** I still [experience both worlds], I still teach. ... I've got a 0.4 position at [the university].

**P7:** I'm the chairman of the [academic centre], which just finished last week, just closed up last week.

### *Invoking Personal Ethics*

Many participants made reference to the need for personal integrity and the willingness to speak out about concerns about commercial activities.

**P3:** I mean the sites in Australia, like the staff in Australia, have just got absolute integrity.

**P13:** In my company, I think if there was something funny going on, like it was bordering on the illegal ... there are well-established procedures for whistle-blowing, and again the company goes out of its way to encourage that, so there's no risk of being allowed to be swept under the carpet.

**P15:** Especially in the role I'm in now, absolutely I can make a call to say, "No, that's not appropriate, we don't do that." And escalate that through.

Several participants emphasized that they would leave a company if they ever felt that their ethical standards were being compromised.

**P12:** I've never really felt compromised, that I've had to lower my standards or back down on my standards. I've never had someone, when I've given really strong advice not to, do it; no one's overridden that. That's why I've stayed for 23 years. If I felt compromised I'd leave.

**P9:** If you've got detrimental information [about the company], there's an ethical obligation to communicate it internally. Invariably, if it's communicated internally, they should be acting. And ultimately if they don't react, people leave and they are whistle-blowing.

### *Invoking Regulation*

Finally, regulation was an important tool available to our participants for navigating between the demands of commercialism and the commitment to social responsibility. Although some regulations were generated by industry or in collaboration with industry, regulations were primarily focused on limiting the power of industry to act with only commercial goals in mind when conducting research, marketing their products, setting product prices, and so on. Thus, by embracing internal and external regulation, our participants were in a stronger position to resist the company's or industry's commercial imperative when they believed such resistance to be necessary.

The reality of working in a commercial environment, in which some people will inevitably push the boundaries, was not denied.

**P14:** We also need to be monitored. So while there is commercial gain in anything, you need to have a really good monitoring process in place. Individuals, people will be people. Adam Smith is right, so I guess we'd be Wall Street. You need to have constant safeguards, either internally applied or sanctions externally applied, you can't just let go.

**P9:** I think it's an industry that's ethical and responsible most of the time, but you will get the odd person who pushes the boundaries, where he will be picked up and given grief.

Our participants spoke about the importance of regulation at many levels, including local laws, international laws, company codes of conduct, industry codes of conduct, auditing by industry and government, and informal checking by competitors.

**P13:** I think [codes of practice] are a good thing. And they're applied. And the reason they're applied and work is because we do on each other, basically. So it's a small world and it's a bit incestuous. So if a company misbehaved, every other company would know about it within 24 hours and would make a complaint.

**P11:** You've got to really protect against fraud, you've got to really audit. Now we audit ourselves to make sure everything is hunky-dory, and ethics committees and TGAs [Therapeutic Goods Administrations] are now coming up to where they are also in the position to audit people.

**P10:** If you talk about regulatory affairs and clinical research, you are working on projects for 12, 24 months, and you really want to ensure that everything, all the i's are dotted and the t's are crossed.

Although regulation was occasionally seen as restrictive, both internal and external regulation were seen to provide a framework for moral and ethical behaviour.

## **Discussion**

In this article, we showed that our participants, all of whom work in the "medical affairs" departments of Australian pharmaceutical companies, were committed to both the social responsibility priorities of medicine and science and to their companies. Further abstraction from our emergent findings showed that, despite the discrepancies and potential conflicts between these commitments, our participants appeared to cope by using two dialectically related strategies:

1. Embracing commercial commitments by reframing them as being like science or medicine (finding common goals, methods, or virtue opportunities).
2. Resisting being overwhelmed by the commercial imperative by maintaining a scientific or medical identity, or by invoking personal ethics or external regulation.

### Theoretical Interpretation: The Institutional Lens

These findings can usefully be viewed through the perspective of institutional theory. Many of our participants' efforts to negotiate their dual commercial and social responsibilities resemble those described by institutional theorists.

What we have identified as Strategy 1 (embracing commercial commitments by reframing them as being like science or medicine in terms of common goals, methods, or virtue opportunities) represents an attempt to reframe aspects of the commercial logic in order to make it compatible with the prevailing scientific logic under which participants began their careers. This has been described in other studies of multiple institutional logics (Nelson 2005). Our participants' efforts to find practices that were conducive to the goals of both commercial success and patient well-being is also similar to the previously recognized strategy of strategic collaboration (see Reay and Hinings 2009), in which distinct goals and identities are maintained but efforts are made to find "win-win" strategies that satisfy the goals of both logics.

What we have described as Strategy 2 (resisting the commercial imperative by invoking ethics or regulation) introduces some new tactics, within a strategic collaboration approach, that we have not seen previously described in the literature. In other words, our participants were comfortable being part of the commercial enterprise but used personal ethics and regulatory mechanisms to retain control over some aspects of the practice.

It is noteworthy that we did not find evidence of the strategy of decoupling or ceremonial compliance, as found by Kitchener (2002). Rather, our participants seemed to embrace both commerce and science/medicine in a holistic fashion. This lack of passive rebellion might not be surprising, given that our participants had voluntarily moved into a new organizational field, rather than have changes to an existing field in which they worked imposed from outside.

With this in mind, we could consider that our participants managed their move from one organizational field (science or medicine) to another (industry) by using techniques to navigate the coexistence of competing logics associated with those commitments (Montgomery 2001; Ham et al. 2011; Iedema et al. 2004; Forbes et al. 2004; Gatrell and White 1996).

### Limitations and Future Research

Our study had a number of limitations, each of which point to the need for further research. First, this was a small qualitative study, and we do not know the degree to which our findings are generalizable. Future qualitative research might usefully extend to commercial departments in pharmaceutical companies (e.g., sales and marketing divisions) and to "parent" companies outside Australia—where the commercial ethos may be more entrenched.

Second, we cannot make fine distinctions between the sub-groups we studied (e.g., clinical trial managers vs. regulatory affairs managers vs. medical directors). Future research might focus on teasing out differences among these groups.

Third, because we were aiming for maximum variability, we did not limit our focus to those themes that were generalizable across all interviews. Future research could focus on identifying those views that all participants have in common and on teasing out reasons for differences between participants.

Fourth, because our findings were emergent, we could not know in advance which themes would prove to be most significant and might need “unpacking.” Additional studies could pursue more targeted questions with participants about how they simultaneously manage the commercial and scientific–medical dimensions and demands of their work, rather than simply allowing this information to emerge from the data. Participants could also be asked more directly about the failings of industry and whether/how they respond personally when misconduct arises.

Fifth, we acknowledge that it could also be argued that our participants were trying to present themselves and their industry work in a more favourable light than is warranted. Triangulation with other methods (such as ethnographic observation and quantitative studies of actual industry behaviours) might help to determine the veracity of these accounts. Nonetheless, we believe that *espoused* values are likely to be significant motivators of future behaviour, irrespective of the degree to which they have been put into practice in the past.

Finally, we note that qualitative research provides only one perspective on a complex phenomenon and that greater understanding of the workings of the pharmaceutical industry would be achieved by combining various qualitative and quantitative methods.

### **Practical Implications**

Despite these limitations, and while we would not suggest that pharmaceutical policy should be changed on the basis of a single qualitative study, our results may have implications for pharmaceutical ethics, policy, and governance. First, anyone negotiating with individuals in the pharmaceutical industry would do well to remember that our results suggest that people working in the medical affairs sections of pharmaceutical companies are likely to be (or wish to be seen to be) committed to scientific and medical goals as well as to commercial goals. In this regard, they might be somewhat different to people with purely commercial backgrounds, working in purely commercial departments such as sales and marketing (as an aside, future research might be warranted to examine whether even the latter group is committed to commerce to the exclusion of scientific and medical goals).

Second, it is important to recognise the wide variety of ways that people in the medical affairs departments of pharmaceutical companies manage the challenge of working with potentially competing commitments in a highly criticised industry. There is little evidence that the commercialism of the industry has completely overshadowed commitments to science or medicine; instead, a set of strategies and techniques appears to enable this group of professionals to operate in a way that does not necessarily privilege one set of commitments over the other.

It is particularly noteworthy that participants in the study found regulation to be empowering in the face of strong commercial pressures. Rather than curtailing their professional autonomy, regulation seemed to give these participants the authority to stand up for and express their (non-commercial) values. Regulation can thus be understood not (only) as a threat to commerce, but (also) as a beneficial way to improve pharmaceutical industry practices by empowering those within industry who want to act with integrity in the face of competing commitments.

Our findings also point to the importance of involving people who work in medical affairs departments of drug companies in decisions about regulation. We have shown that industry professionals are not necessarily opposed to being regulated and are likely to be able to provide useful information as to how regulation can best help them to resist excessively strong commercial forces. Similarly, ethical education could be provided not simply to highlight the moral failings of industry (which tends to be the focus of much pharmaceutical ethics) but rather to provide industry professionals with the conceptual tools they might need to stand up for their beliefs in the face of company pressure to privilege commerce over other important considerations.

None of this is to suggest that industry should be left to its own devices in determining how, and to what extent, it is regulated. First, our participants are not representative of the industry as a whole, which also contains individuals who are likely to be more committed to the commercial imperative. Second, even our participants expressed some ambivalence about the need to actively resist the commercial imperative. For example, in their efforts to resolve cognitive dissonance, our participants sometimes attempted to find similarities between commerce and science/medicine (strategy 1), rather than emphasize the role of regulation. Moreover, we detected a dialectical movement between the two strategies, which means that employees of industry may shift from one position to another: At times, they might be willing and able to separate themselves from, and moderate, the commercial imperative (strategy 2). At other times, their reframing efforts (strategy 1) might make it more difficult for them to do so.

Nonetheless, it seems wise to remember, when engaging with individuals who work in the pharmaceutical industry, that these individuals are likely to have finely honed strategies in place for managing potentially competing commitments in the face of external criticism; that one size does not fit all when it comes to everyday pharmaceutical ethics; and that, therefore, different approaches need to be used if we want to ensure that commercial goals do not override all other considerations. In other words, we do not argue against a critical stance to industry, but rather we suggest that a more nuanced and cooperative approach might be more productive and may be more in line with the contemporary realities of the pharmaceutical industry.

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**Table 1. Research participants**

	Gender	Age	Previous profession	Current role
P1	M	50-60	Physician and medical researcher	Medical director
P2	M	30-40	Physician	Medical affairs manager
P3	F	50-60	Pharmacist	Senior manager in clinical research
P4	F	50-60	Pharmacist and biomedical researcher	Senior manager in regulatory affairs
P5	F	40-50	Pharmacist and academic researcher	Internal scientific advisory role
P6	M	50-60	Academic health economist	Senior manager in pricing and reimbursement
P7	M	60-70	Physician and clinical researcher	Medical director
P8	M	50-60	Physician	Medical director
P9	M	50-60	Pharmacist	Senior manager in pricing and reimbursement
P10	M	40-50	Pharmacist	Senior manager in clinical and regulatory affairs
P11	F	60-70	Biomedical researcher	Senior manager in clinical research
P12	M	50-60	Pharmacist and biomedical researcher	Medical director
P13	M	50-60	Pharmacist and biomedical researcher	Senior manager in pricing and reimbursement
P14	M	40-50	Pharmacist	Senior manager in pricing and reimbursement
P15	M	50-60	Pharmacist	Senior manager in clinical research

**Figure 1. Strategies used to manage competing commitments**

