Melancholy and the Infinite Treatments

An Investigative Study into the Marketing of Antidepressants

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<u>Abstract</u>

In the 1990s the estimated prevalence of depression was two thousand times higher than in the 1960s (Leader 2008a; 2013). This astronomical rise in depression corresponded with the launch of blockbuster antidepressants released in the late 1980s: selective serotonin reuptake inhibitors (SSRIs). Perhaps the most well-known of these drugs is Prozac, which, as evidenced by the book and subsequent film *Prozac Nation*, became a pop culture phenomenon (Wurtzel 1994; Skjoldbjærg 2001). This thesis argues that the increase in depression diagnoses after Prozac hit the market is reflective of a broader narrative within the treatment area. Historically, what constitutes a pathological low mood has invariably been defined by those purporting to have a treatment. Indeed, the marketing of treatments routinely corresponds with diagnostic marketing. In contemporary societies, treatment is primarily defined and controlled by mammoth commercial entities: multinational corporations. The proposed solution is invariably pharmacological in the form of drugs such as Prozac.

Adopting an investigative methodology inspired by traditional social scientists, such as Derek Layder (1993), and investigative journalist Mark Lee Hunter (2011), this thesis examines the marketing activities of antidepressant manufacturers. The long shadow cast by Prozac over the depression treatment market is unavoidable and integral to understanding contemporary issues in this area. With this in mind, it is essential to use an approach which embraces and foregrounds the historical context. Furthermore, as Layder (1993) argues, history envelops every aspect of the research process, and, as such, history should be prioritised and treated as a method in and of itself.

This research identifies evidence which suggests that the increase in depression diagnoses and antidepressant prescriptions is due, in part, to unethical marketing techniques, or, more specifically, covert marketing that targeted medics and charities. For example, doctors were flown to exotic islands by pharmaceutical companies, a charity was paid to covertly promote marketing messages, not to mention that I could handwrite this thesis a thousand times over with pens sporting antidepressant brand names. These activities are indicative of a pharmaceutical industry driven by medicalisation, or pharmaceuticalisation. However, in light of public criticism over such practices companies have subsequently endeavoured to ensure that the promotion of

antidepressants follows ethical guidelines. Today, there are more rigorous regulations pertaining to gift giving and hospitality, and, indeed, this research verifies this shift towards greater transparency in these practices. However, such improvements are mitigated by what Abraham (2008) designates as 'neo-liberal corporate bias.' Hence, as pharmaceutical companies self-regulate their marketing activities, this regulation is often refracted through self-interest and the profit motive. Overall, this investigation demonstrates that depression continues to be defined by the Big Pharma companies that promote drug treatments, which leaves the door open for future research when the depression treatment du jour inevitably changes.

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Abbreviations

| 5-HTP | 5-Hydroxytryptophan |
|--------|--|
| ABPI | The Association of the British Pharmaceutical Industry |
| BMJ | British Medical Journal |
| BNF | British National Formulary |
| CBT | Cognitive Behavioural Therapy |
| CCBT | Computerised Cognitive Behavioural Therapy |
| CINP | Collegium Internationale Neuropsychopharmacologium |
| CPD | Continuing Professional Development |
| D/ART | Depression Awareness Recognition and Treatment |
| DA | Depression Alliance |
| DDC | The Defeat Depression Campaign |
| ECT | Electroconvulsive Therapy |
| FDA | Food and Drug Administration |
| FOIA | Freedom of Information Act |
| GP | General Practitioner |
| GSK | GlaxoSmithKline |
| HCP | Healthcare Professional |
| KAM | Key Account Manager |
| KOL | Key Opinion Leader |
| MAOI | Monoamine Oxidase Inhibitors |
| MHRA | Medicines and Healthcare Products Regulatory Authority |
| MORI | Market & Opinion Research International |
| NBF | New Biotech Firm |
| NHS | National Health Service |
| NICE | National Institute of Healthcare Excellence |
| NISCHR | National Institute for Social Care and Health Research |
| ONS | Office for National Statistics |
| PCMPA | The Prescription Medicines Code of Practice Authority |
| PR | Public Relations |
| PSR | Pharmaceutical Sales Representative |
| RCGP | Royal Collage of General Practitioners |

| RCPsych | Royal College of Psychiatrists |
|----------|--|
| SKB | SmithKline Beecham |
| SSRI | Selective Serotonin Reuptake Inhibitor |
| TCA | Tricyclic Antidepressants |
| tDCS | Transcranial Direct Current Stimulation |
| TMS/rTMS | Transcranial Magnetic Stimulation/Repetitive Transcranial Magnetic |
| | Stimulation |
| USP | Unique Selling Point |
| VNS | Vagus Nerve Stimulation |
| WHO | World Health Organisation |
| WiPC | Work in Progress Campaign |

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Part 1: Preliminaries

1: Introduction

1.1 Introduction

Over the past decade alone, prescriptions for antidepressants have doubled (NHS Digital 2017). Resultantly, approximately one in ten adults are now estimated to be on these drugs at any given time (Lewer et al. 2015). One would expect that when a treatment becomes popular the symptoms addressed by a treatment would decrease, whilst the number of diagnoses would stay the same, capped by the condition's natural occurrence within a population. However, after blockbuster antidepressants, such as Prozac, hit the market, diagnoses of depression have increased. Leader (2008a) notes that in the 1960s the prevalence of depression was estimated at 50 per million, whereas by the 1990s this had increased to 1 in 10. The most recently available figures from the Office for National Statistics (ONS) estimate that up to 1 in 5 people currently experience depression or anxiety (ONS 2018). Furthermore, the World Health Organisation (WHO) estimates that 1 in 4 people in European countries experience common mental illnesses such as depression and anxiety every year (World Health Organization 2017).

For some, the rising number of depression diagnoses signifies a reduction in stigma around mental illness. Stigma is known to prevent individuals from seeking treatment for depression (Barney et al. 2006). Therefore, perhaps struggling individuals now feel more comfortable talking about their problems, which, in turn, leads to an increase in the use of antidepressants as more individuals gain access to treatment. Similarly, if more people present to their doctors with symptoms of eczema, then we would expect to see a similar increase in the prescription of emollients and steroid creams. This proposed explanation for the exceptional growth of antidepressant prescriptions in the UK over the last quarter of a century can be described in economic terms as a simple supply/demand model. That is to say, as more individuals present to their GPs with depressive symptoms, there is a greater demand for antidepressants which is met by an increase supply by manufacturers, and finally an increase in prescriptions. However, we must not ignore the impact that suppliers can have on demand.

As Leader (2008b) points out, the concept of depression itself is inextricably linked to its pharmaceutical treatments. Leader argues that 'it seems to have occurred to no one purveying a medical cure for depression that the remedy may function as a mirror for the malady' (Leader 2008b, p. I). Whilst I am in full agreement with Leader's (2008b) identification of a link between illness and its treatment, I question whether this mirroring is unintentional and unnoticed by antidepressant manufacturers.

More critically, scholars argue that diagnoses of depression have expanded far beyond the truly unwell population to include individuals experiencing normal human emotions (Dowrick and Frances 2013). This phenomenon is commonly referred to as medicalisation (Conrad 1992; Conrad and Leiter 2004; Conrad 2005; Conrad and Schneider 2010; Smith 2014). Medicalisation can be a relatively neutral phenomenon that occurs because of natural shifts in societal norms and priorities. Childbirth is an illustrative example of a practice which has become subject to medicalization over the last century, and, indeed, few would argue that this has not had a positive impact on the experience and outcomes of childbirth. Some critics have gone one step further, ascribing the increase in diagnoses to pharmaceuticalisation (Abraham 2010). However, pharmaceuticalisation specifically refers to the expansion or blurring of the boundaries between illness and drug treatments to increase pharmaceutical demand (Abraham 2010). This idea of pharmaceuticalisation is in agreeance with Conrad's (2005) finding that medicalization had become increasingly driven by commercial and market factors, namely, pharmaceutical companies.

This thesis attempts to apply the concept of pharmaceuticalisation/medicalisation to understand depression and the growth of the antidepressant market, whilst, simultaneously, using depression as a case study through which to extend the concept of pharmaceuticalisation by looking at the business management or marketing dimensions of this process. Specifically, this is done by examining the business interactions between pharmaceutical companies and their audiences. In so doing, this thesis contributes to socio-medical literature by highlighting the business aspect of pharmaceuticalisation, whilst also casting light on an industry that hitherto has received scarce attention within the discipline of business management. Antidepressants have been used for the treatment of depression for decades (Improvement 1986; Gardner 2003; Lawlor 2012). Hanganu-Bresch (2011, p167) notes that the very existence of antidepressant drugs prompts debate over what constitutes health, illness and, on an even deeper level, humanity. Hangani-Bresch's (2011) observation is especially pertinent to the case of Prozac. A member of the most popular type of antidepressants, SSRIs, Prozac became a cultural phenomenon with it proponents arguing that it rendered its takers better human beings (Kramer 1994).

SSRI prescriptions continue to rise in the UK, with their success often being attributed to the marketing efforts of pharmaceutical companies (Gardner 2003; Greenberg 2010). In their paper for the British Medical Journal, Light and Lexchin (2012) observe that pharmaceutical companies spend nineteen times more on marketing than research and development.

For almost half a century, there has been extensive debate over the use of marketing and advertising methods to promote drugs aimed at treating mental illness. However, when comparing the issues raised by authors such as Goldman and Montagne (1986) and those raised by Gardner (2003), it is apparent that, whilst critical ideas are gaining traction, the core debate has changed very little during this period. Both papers argue that advertising antidepressants leads to the over-medicalisation of depression. Although the debate itself has been ongoing for decades, there has been a dearth of contributions from business schools. Organisations are at the heart of arguments about the increase in depression diagnoses and antidepressant prescriptions. Whether it is pharmaceutical companies, health authorities, third party advertising agencies or British royal collages, large organisations are front and centre in this topic. It is therefore anticipated that conducting investigative work into this topic, from within the broad discipline of business management, will provide a new perspective and make a unique contribution to extant understanding of pharmaceuticalisation as a product of business and marketing decision-making. The case study for exploring this process of pharmaceuticalisation is depression and antidepressants.

One reason why there has until now been scarce business research in this area is perhaps down to difficulties in gaining access. In fact, the pharmaceutical industry itself

has a reputation for extremely limited levels of transparency (Dhalla and Laupacis 2008; McCubrey and Rah 2009; Poitras and Meredith 2009; Lee and Kohler 2010; Ross et al. 2012; Goldacre et al. 2013). A novel methodology designated as investigative social science (Douglas 1976; Levine 1980; Ho et al. 2006) offers an alternative mode through which business scholars can research the covert marketing of antidepressants. Most commonly utilised in sociology, investigative social science describes the incorporation of techniques originally developed within investigative journalism into traditional social science research. Within this approach, data is gathered by 'following the line of enquiry' and allowing different modes of data collection to inform each other. For example, a potential interview participant may be identified and contacted from a documentary source. Investigative social science is deemed to be especially appropriate for topics involving issues of transparency as it allows for an in-depth, creative exploration of what initially may appear to be small, unsupported findings. Following in the tradition of investigative journalism, findings are corroborated by inviting viewpoints from all sides of a debate. How investigative social science specifically applies to the present research will be discussed in detail in the methods chapter.

Through an investigative approach, this research aims to explore the role of various organisations (public and private, but also third sector) in mediating and manipulating the popular understanding of depression, and in terms of increasing the commodification of its treatments. Marketing messages and the underlying motives will be discussed in depth, as well as practitioners' perspectives on these messages. Other sources of information on depression and its treatments will also be examined, such as disease awareness campaigns, television programmes and websites. The socio-political history of psychiatry will also be dissected in light of the arguments that the profession used depression to legitimize itself and is too close to the pharmaceutical industry (Moncrieff et al. 2005; Insel 2010). Ultimately, this research aims to contribute to the debate over whether the increase in depression diagnoses and growing antidepressant prescriptions, is due to disease mongering, medicalisation or pharmaceuticalisation. Through examining the business activities of antidepressant manufacturers, this research contributes to the socio-medical literature which coined the aforesaid terms. This research marks the first investigation within the discipline of

business management into antidepressant marketing. In so doing, this thesis thus contributes to both business management and socio-medical literature by providing a new understanding of pharmaceuticalisation, medicalisation and disease mongering as products of business activities.

Theoretically, this thesis is underpinned by an approach developed by Michael Billig. Billig (2013) argues that social analysis should not rely on a single approach, but rather, draw on different theoretical ideas. Therefore, this thesis does not shoehorn findings into a singular, overarching theory. Rather, a 'light-touch' approach is used, that, when appropriate, draws upon a number of useful theories in a magpie-like fashion.

1.2 An Overview of the Thesis

Chapter 2, which follows this presents a review of existing literature, and identifies how the present research will contribute to the field. More specifically, it situates the research within the boarder literature of antidepressant marketing and makes the case that further research needs to be conducted, especially from management schools.

Chapter 3 is the methods chapter. There, I provide a detailed account of the methods of data collection employed in the research, before proceeding to delineate the epistemological and ontological perspectives which informed their selection. Particular attention is given to the concept of 'investigative social science' which permeates every aspect of this research. The methodology utilised in this research also draws upon traditional social scientists, such as Becker (2007), Layder (1993) and Billig (2013), as well as investigative journalists like Hunter (2011). The argument put forward in this chapter is that this approach allows me to investigate a powerful industry characterised by low-levels of transparency, and better equips me to research issues of broad societal importance (Marinetto 2015).

In the methods chapter, I draw upon the work of Derek Layder (1993) to make the case for historical analysis being classed as a method in and of itself. From this perspective, chapters 4 and 5 which are entirely historical can be considered the first findings chapters. In chapter 4, I draw upon secondary sources to trace the genealogy

of pathological low mood from its humble beginnings in the form of acedia and melancholy, to the modern-day diagnosis of depression. Chapter 5 explores the parallel history of depression treatments. Through examining the evolutionary history of depression and its treatments an integral narrative emerges: depression has consistently been framed by the organisations who claim to treat it. The church explained it in terms of demon possession, Freud as repression, and pharmaceutical companies as a chemical imbalance. The chapter proceeds to outline how we have yet to fully understand the mechanisms and causes of depression. In other words, a vacuum exists in our collective knowledge, and as will be shown in this thesis, wherever there is a vacuum, interested parties will step in.

Chapter 6 turns its attention to the manufacturers of antidepressants: Big Pharma. As noted previously, this thesis is defined by historical context, and, as such, this section begins by exploring the history of the pharmaceutical industry itself. The pharmaceutical industry occupies a unique political position in the UK, and thus understanding its operation and its relationship to the NHS is integral for understanding the antidepressant market. Chapter 7 then focusses on the industry employees who disseminate marketing information. Pharmaceutical sales representatives (PSRs), commonly known as 'drug reps', are almost as iconic as Prozac itself, appearing in Hollywood films such as Love and Other Drugs, John Grisham novels, and television program such as The Simpsons and The Big Bang Theory. They are the foot soldiers of the industry. When a new antidepressant is released to market, prescribers often learn about it (either directly or indirectly) through PSRs. PSRs are often characterised in the media as manipulators who seduce doctors into prescribing their medicine at any cost. This chapter interrogates this popular depiction. Drawing upon interviews with eight PSRs who have sold antidepressants, I examine what it means to be a pharmaceutical sales representative. Further to this, I question the extent to which pharmaceutical sales representatives use manipulative tactics to influence prescribing.

Chapter 8 focusses on the frequent targets of antidepressant marketing: healthcare professionals. Healthcare professionals are the gatekeepers of the NHS. On a micro level they hold the power of the prescription pad, and on miso and macro levels they

are involved in decisions of drug approval and whether a particular hospital or health board should pay for a drug. It is as gatekeepers that healthcare professionals find themselves most purely on the receiving end of marketing efforts, however many healthcare professionals also collaborate with industry. I describe some such healthcare professionals as locksmiths. They advise companies on how to appeal to gatekeepers. Historically healthcare professionals who chose to collaborate with pharmaceutical companies have been depicted as 'greedy pigs'. However, my interviews with collaborators indicates a more complex, symbiotic relationship. Once again, as seen in chapter 5, a vacuum emerges. Training budgets for healthcare professionals halve, and antidepressant manufactures present an opportunity for free education.

In the UK it is illegal to advertise prescriptions directly to the public. This creates a challenge for antidepressant manufacturers looking to increase demand for their new product. It is not, however, illegal to promote awareness of a condition treated by prescription medicines. The corporate sponsorship of depression awareness campaigns has been commonplace in the UK since the 1990s. In the history chapters the case was made that depression has been consistently defined by those who treat it. Through providing information about depression to the public corporate funded depression awareness campaigns are a key component of this narrative. Chapter 9 dissects corporate funded depression awareness campaigns in the UK from the very first one in 1992, to the most recent in 2016. What emerges is a shift in agenda, from using campaigns to covertly disseminate marketing messages, to a more political motive. Antidepressant manufacturers now align themselves with charities to bask in their 'political and rhetorical power' (Loseke 1997). Using the symbolic resources of charities to improve their reputation and aid in getting their product approved by health boards and formularies.

Finally, the last findings chapters look towards the future of the antidepressant market. The history chapters presented the narrative that antidepressants may be usurped as the primary treatment option for depression, and the industry responsible for their development may be heading towards a 'winter of discontent'. However, chapters 6,7,8 and 9 demonstrate how the industry is adapting to recent challenges. These short final chapters present the threats (chapter 10) and opportunities (chapter 11) facing antidepressant manufacturers. Are we entering a new era of depression treatment where symptoms of low mood will be treated with virtual reality or new medical devices? Or, can pharmaceutical companies continue their hegemony over the depression treatment market?

Ultimately this research makes the argument that depression has been consistently defined by those who claim to provide a treatment. Most recently this has been done by pharmaceutical companies which have, at times, used unethical methods to promote the condition and increase antidepressant sales. This has resulted in scandals which have proved unprofitable for the industry. Resultantly the industry has increased regulation and improved overt practices which have been publicly criticised. However, as the industry is both self-regulated and required to make a profit, covert activities, which have not been subjected to public scrutiny remain unregulated.

2. Literature Review

2.1 Introduction

The ethical status of the pharmaceutical industry or 'Big Pharma' is a contentious subject, receiving attention from all corners of both academia and the media. Critics argue that the pharmaceutical industry is corrupt, wielding too much power which ultimately results in a poorer deal for patients (Goldacre, 2012). Whilst criticism of the pharmaceutical industry is widespread (Arndt 2006; Brody 2007; Dumit 2012; Götzsche 2013), others however, emphasise that the industry plays an essential role in both the economic and public health of society (Leisinger 2005,2009,2011).

I will be reviewing four types of literature relevant to this thesis: literature on Big Pharma, literature on pharmaceutical marketing, literature on pharmaceuticalisation and literature on antidepressants. This literature review will begin by drawing upon relevant literature to briefly establish what is meant by 'Big Pharma': its antecedence, and its connotations. Attention will then be turned specifically to the marketing practices of pharmaceutical companies, with an emphasis on the ethical debates surrounding such practices. Critical concepts such as disease mongering, medicalisation and pharmaceuticalisation will be defined and discussed drawing upon key literature from the disciplines of marketing, medicine, sociology, medical anthropology and business ethics.

Subsequent to acknowledging the respective strengths and limitations of the academic literature, examples of critical journalistic literature on the pharmaceutical industry will also be considered. After reflecting on the themes and concepts identified in both the academic and alternative literatures, the manifestation of such concepts in the field of psychiatry will them be presented and discussed. Finally, I will situate the present research within extant literature and debates, discuss what theories will be drawn upon, and delineate how the research will contribute to the field.

2.2 Studying 'Big Pharma'

Big Pharma is the nickname given to the vast global pharmaceutical market which in 2016 had a revenue of over \$1 trillion USD (Statista 2018). Big Pharma is also

commonly used abstractly to refer to some or all of the following large companies: Johnson & Johnson, Roche, Pfizer, Novartis, Sanofi, GlaxoSmithKline, Merck & Co, AbbVie, Bayer, Abbott Laboratories, Eli Lilly & Co and AstraZeneca amongst others. Whilst these companies are the largest in terms of revenue, and most of them have released antidepressant products over the past three decades, the industry is also comprised of more specialist, medium-sized companies. The key smaller players in the antidepressant market are the German company, H. Lundbeck, and the French company, Servier. To provide a comparison, last year Servier declared a revenue of around a quarter of that declared by the Prozac manufacturer, Eli Lilly (Servier 2018). Although these companies are smaller, for brevity I am using the term Big Pharma to refer to all relevant players in the market, which, in terms of antidepressants, includes Servier and H. Lundbeck.

Whilst the pharmaceutical industry is occasionally depicted as comprising innovative companies that produce lifesaving drugs (Vallée 2013), it is more commonly presented in the media as ruthless, dishonest and greedy (Zwick 2010). Resultantly, public trust in the pharmaceutical industry is consistently waning (Brown and Calnan 2010; Kata 2012; Fort 2014; Hernandez et al. 2014). Leisinger (2005) argues that such criticisms are due, in part, to a dissonance between the industry's self-perception of its responsibilities and the perceptions of the wider public, whereas Hernandez et al. (2014) cites public scandals as the reason for diminishing trust. The following section establishes what precisely is meant by 'Big Pharma', who it is comprised of, and what its purpose is.

As noted by Leisinger (2005), there is often a conflict between Big Pharma's selfperception of its role in society and how other stakeholders, such as the general public, view its role. Whilst Leisinger (2005) examines this dissonance specifically in relation to corporate social responsibility (CSR), it is also possible that this dissonance exists in other business activities, such as marketing communications. There is an emergent body of mainstream journalistic literature presenting critical perspectives of the pharmaceutical industry and its use of marketing (e.g.Healy 1997,2004; Angell 2005; Law 2006; Brody 2007; Greenberg 2010; Goldacre 2012; Healy 2012c; Davies 2013; Götzsche 2013). Although, of course, this mainstream literature is not subject to the peer-review process that academic journal articles go through, that is not to say that these books are without value.

Goldacre's (2012) book *Bad Pharma* is perhaps the most well-known of its kind in recent years. Goldacre (2012) provides an overview of the ethical issues facing the modern pharmaceutical industry, and his book is aimed at a broad target audience of practitioners, pharmaceutical industry employees and the public. Previously employed as a columnist for The Guardian, in addition to being well-published in academic journals (Goldacre 2007,2009; Goldacre et al. 2013), Goldacre illustrates how investigative journalistic techniques and rigorous academic evidence can be combined effectively in the exploration of potentially hidden phenomena.

Similarly, *White Coat Black Hat* by(Elliot 2010) utilises journalistic methods to explore anecdotal evidence about the relationship between medicine and the pharmaceutical industry. Focusing on the historical development of the marketing of pharmaceuticals, Elliot (2010) uses narrative to propose how well-meaning individuals can become coproducers of unethical behaviours.

These publications, and others like them, utilise the methodology of investigative journalism. Although journalistic techniques are often criticised within academia (May 1994, p. 133), Hilgartner (1990) argues that the criticism and dismissal of popular science within academia may operate as a device to reinforce hierarchy and safeguard the position of academia at the top of that hierarchy. There is also a line of argument that suggests that journalism is actually becoming increasingly scientific in nature (Meyer 2002). Such literature, which Mayer terms 'precision journalism,' shows increasing rigour and blurs the lines between social science and journalism (2002, p. vii). The scientific turn in journalism is also evident in data journalism, which will be discussed later in the chapter.

Although some branches of journalism are demonstrating increasing rigour, it is impossible to ignore the trend towards less reliable content in other areas. In recent years journalism has been subject to increasing amounts of criticism. One accusation is that journalism is becoming 'churnalism', simply recycling content from pubic relations wires (Davies, 2008). Moreover, after the 2016 US election the term fake news rose in popularity. Initially the term was used to describe news which was factually untrue, however the term has since become a political weapon typically used against mainstream liberal news sources (Tandoc jr. et al. 2018). It therefore cannot be assumed that all journalism is rigorous and of a high quality, rather, each enquiry must be appraised on its own merits.

Whilst Goldacre's (2012) and Elliot's (2010) work is somewhat journalistic in nature, this does not necessarily detract from the validity of their findings. Both authors utilise investigative approaches to explore corruption within an enormously powerful and profitable industry. Furthermore, by presenting their findings and discussions in narrative form, such books are more accessible to a broader audience, and, as such, have a greater potential to impact the social world.

Later in this chapter, I suggest that marketing literature is limited by the needs and interests of its target audience of pharmaceutical industry employees. Similarly, popular non-fiction can also be limited by an awareness of its audience. Consequently, the commercial element of these publications cannot be ignored. Given that it is displayed on the shelves of retailers such as WHSmith, Waterstones, and increasingly major supermarkets, non-fiction is encumbered by a responsibility to entertain readers as well as educate them. Hence, awareness of the commercial readership may contribute to the inclusion of somewhat overstated claims, such as 'the whole edifice of medicine is broken' (Goldacre 2012, p. ix). Given that books like Goldacre's (2012) acknowledge that pharmaceutical funding can skew the information presented in educational materials and journal articles, it is not altogether unreasonable to question whether funding from publishers can skew the information presented in these kinds of publications.

It is thus important to be cognisant of the entertainment aspect when reading investigative non-fiction, and to read such literature with the same critical eye one would apply to academic literature. Provided that one identifies and acknowledges the potential biases of mainstream literature, it can still be utilised as a useful resource. In fact, the biases presented in such literature can provide additional useful information about the audience (Fitzgerald 2007, p. 283). As acknowledged by Becker (2007), whose work will be discussed in more detail in the methods chapter, every source is expedient for telling us about something, it simply takes time and thought to identify what that something is.

2.3 Studying Big Pharma Marketing

Attention will now be turned to the marketing practises of the pharmaceutical industry, and the ethical implications of these practices. In an article for the BMJ, Light and Lexchin (2012) found that the industry spent 19 times more on marketing than it did on research and development. Further to this, Malerba and Orsenigo (2015) posit that marketing has become the primary function of pharmaceutical companies, an idea which will be discussed in more detail in chapter 6.

As with every aspect of the pharmaceutical industry, the marketing of drugs is conceptualised differently by different populations. In the literature, such differences are often predetermined by the discipline in which the author works. The key disciplines in discussions of pharmaceutical marketing are marketing, medicine, sociology, medical anthropology and business ethics. This section will discuss in turn the manifold contributions made to pharmaceutical marketing by each of these academic disciplines.

2.3.1 Marketing Studies and Pharma Marketing

Whilst the literature in other disciplines focuses on the patient or 'end consumer' of a pharmaceutical transaction, marketing literature is primarily concerned with the vender, that is, the pharmaceutical companies themselves. Marketing literature tends to be written from the perspective of the industry itself, discussing the benefits of marketing methods for pharmaceutical companies. This is exemplified by the extensive literature on the use of drug reps to market pharmaceuticals (Scharitzer and Kollarits 2000).

Such literature tends not to acknowledge any potential conflict of interest involved in marketing pharmaceuticals to healthcare professionals (Scharitzer and Kollarits

2000), focusing instead on how marketing methods can be used to maximise pharmaceutical demand (Smith and Cooper-Martin 1997).

The critical view of pharmaceutical marketing that one encounters in some medical literature is less evident in the marketing literature. What the critical medical literature refers to as 'disease mongering' (Arndt 2006; Moynihan and Henry 2006), marketing literature describes as 'disease branding' and 'condition branding' (Angelmar et al. 2007).

Literature on disease branding tends to frame itself as being concerned primarily with educating the public about diseases, their symptoms and cures. The credibility with which authors present this stance however, varies considerably. For example, both Angelmar et al. (2007) and Parry (2003) write enthusiastically about the benefits disease branding poses to pharmaceutical companies and their profitability. In doing so, Angelmar et al. (2007) and Parry (2003) align themselves more with traditional marketing objectives, such as sales and profit, and less with public education. This is exemplified by the branding strategies advanced by Parry's (2003). Parry (2003) proposes three key condition branding strategies: increasing the perceived importance of a disease; reducing stigma around a disease; creating a new condition and then introducing a new product (drug) to meet the needs of the new condition.

Parry's (2003) substitution of the word product for drug is indicative of a wider underlying assumption inherent to much marketing literature, which is that pharmaceuticals are no different from standard consumer products (Parry 2003; Angelmar et al. 2007; Parsons 2007).

This view, which could be defined as the product-based view of pharmaceuticals, has been criticised by authors from other disciplines (Goldacre 2012). These authors argue that such a view is ultimately harmful to patients for whom the differences between two drugs has a greater impact than the differences between two standard commodities, such as toilet paper or perfume. It is worth noting that at the time of publication, Parry was an employee of the pharmaceutical company, GlaxoSmithKline, and therefore it is possible that his views may have been reflective of those held across the industry at that time.

A second form of disease branding literature, predominantly coming out of a public services marketing perspective, is less overt about its links to treatment (Long et al. 2008). This strand of literature aligns itself more with what it frames as desirable public outcomes as opposed to financial ones (Lefebvre and Flora 1988; Long et al. 2008), and therefore bears some resemblance to socio-medical literature.

Regardless of whether marketing literature adopts either a positive (Parry 2003; Angelmar et al. 2007) or neutral (Long et al. 2008) stance towards the pharmaceutical industry, it tends to be criticised heavily by medical authors. In contrast to the claim that disease branding and condition branding educate the public, Hall and Jones (2008) argue that they are instead used as 'a deliberate method of increasing markets for pharmaceutical products'. Furthermore, Hall and Jones (2007, cited in Hall and Jones 2008) note that only profitable diseases and conditions tend to be branded in this way.

Whilst the marketing literature does vary in terms of its perceived motives and industry links, the amorality that characterises the literature from this perspective is almost universal. Having said this, Parsons (2007) is one author who does acknowledge the ethical debate around disease branding.

Parsons presents disease branding as an illustrative case through which to apply her framework 'Five Pillars of Ethics for Public Communication' (Parsons 2004, cited in Parsons 2007), which she purports could be used to "operationalize ethics" in marketing communications decision-making (Parsons 2007).

Parsons' (2007) paper stands out in its discipline due to its direct acknowledgment of the ethical dimension of pharmaceutical marketing. However, Parsons (2007) only engages with the debate insofar as it can benefit pharmaceutical companies. By presenting disease branding as a way of 'neatly sidestepping' the ethical criticisms associated with drug branding, Parsons (2007) can, simultaneously, acknowledge the ethical debates whilst maintaining the status quo of her field.

In summary, marketing literature on pharmaceutical marketing tends to be amoral and treats drugs as analogous to standard consumer products. Given that this discipline is predominantly populated by former and present pharmaceutical company employees (Parry 2003), it is likely that this literature best reflects the values and assumptions of the companies themselves.

2.3.2 Medical Anthropology

Medical anthropologists have written extensively on many aspects of pharmaceutical industry practices (Van der Geest et al. 1996; Rasmussen 2004), including the emergence of literature in the last decade on marketing (Oldani 2004; Martin 2006).

Medical anthropological literature on pharmaceutical marketing tends to utilise qualitative methods, such as ethnography, in-depth interviews and documentary analysis. These methods generate, deep, complex insights into marketing methods, as well as the historical and contextual factors which precede marketing decisions. This contextual background is described by medical anthropologists as the 'moral economy' of the pharmaceutical industry (Rasmussen 2004, p. 3; Martin 2006, p. 158).

Utilising this concept of the moral economy, Martin (2006) explores the attitudes of employees within the pharmaceutical industry during the 1950s and 1960s, when psychoactive drugs such as antidepressants first appeared on the market. Martin (2006) goes on to present the ambivalence of pharmaceutical industry employees today, using data collected from interviews with existing employees working in pharmaceutical marketing. Martin's (2006) analysis of the historical antecedents of phenomena is characteristic of her field as a whole.

Described as an 'autoethnography' and a 'memory ethnography', Oldani's (2004) research predominantly draws upon historical data, especially his own experiences of working as a pharmaceutical sales representative. Given that Oldani's (2004) perspective has shifted since exiting the profession, he claims to be able to remember

and reflect critically on the opinions and ideas of his previous 'native' self. Whilst the validity, reliability and generalisability of Oldani's (2004) work can be criticised, it nevertheless offers key insights into the lived experience of a pharmaceutical sales representative which is impossible to explore without such biases.

Both Martin (2006) and Oldani (2004) exemplify the primary occupation of the discipline with narratives from pharmaceutical employees. This presentation of industry beliefs and understandings can, to some extent, align the literature with marketing literature, however, in contradistinction to marketing literature, medical anthropological literature acknowledges the ethical and moral implications of marketing methods, through the discussion of the moral economy (Martin 2006), and through the presentation of critical arguments (Oldani 2004).

2.3.3 Business Ethics

Whilst neither the marketing nor medical fields typically address ethical debates related to 'Big Pharma' directly, the field of business ethics focuses primarily on questions such as 'How can a corporation, given its economic mission, be managed with appropriate attention to ethical concerns?' (Goodpaster 1991, p. 53) By concerning itself with questions of ethics, allied with an understanding and awareness of the wider business context, business ethics presents an interesting potential framework through which to analyse the activities of the pharmaceutical industry.

There is a large body of literature on the ethics of marketing and selling to consumers within business ethics (e.g. Mulki et al. 2009), in addition to a small amount of literature examining the use of direct to consumer marketing to advertise pharmaceuticals (Parker and Pettijohn 2003), and the CSR of product recalls (Cheah et al. 2007). However, the discussion of the ethics of marketing pharmaceuticals has hitherto received limited attention in the academic literature. Buckley's (2004) paper 'Pharmaceutical Marketing – Time for Change' is one of the few papers within this perspective that addresses ethical debates pertaining to pharmaceutical marketing. In contrast to the medical literature, Buckley (2004) acknowledges that the remit of the pharmaceutical industry is to make a profit and draws attention to the wider market forces and structures that influence potentially unethical behaviour.

By examining the industry from a business ethics perspective, Buckley (2004) is thus able to, simultaneously, be critical of certain marketing activities, such as those that contribute to 'disease mongering', whilst understanding the role of underlying market forces. In so doing, she is able to make credible normative suggestions. Although Buckley (2004) successfully provides an overview of the ethical concerns associated with pharmaceutical marketing, there is little research of this kind that has been conducted since and, today, over a decade after the publication, the industry is likely to have changed.

The paucity of business ethics literature examining the ethics of pharmaceutical marketing is indicative of a polarisation within the literature, which will be discussed in the following section.

2.3.4 Evaluation of Academic Literature

Thus far, the review of the academic literature has discussed the ethical status of the marketing practices of the pharmaceutical industry and identified a polarization in the respective approaches. At one end of the scale, authors within socio-medical literature have a tendency to voice strong criticisms against the marketing practices of the pharmaceutical industry, to the extent of being accused of bias (Rubin 2004). Such literature is almost wholly concerned with the impact of marketing practices upon patient welfare (e.g. Wazana 2000; Morgan et al. 2006; Fugh-Berman and Ahari 2007), and although the field has yet to demonstrate a conclusive link between marketing and patient outcomes, the presence of this discussion in the literature testifies to the ethical debates. However, this literature fails to acknowledge the wider context of the pharmaceutical industry, most notably the role of market forces. The failure to adequately acknowledge these factors renders the recommendations generated by these papers less applicable. Furthermore, the integrity of the literature as a whole is partially undermined due to the conflictual relationship between medical journals and the pharmaceutical industry. However, the nature of this relationship, and its impact on the legitimacy of journal content, is hotly debated (Morgan 1984).

At the opposite end of the spectrum, traditional marketing literature tends to present an amoral view of the pharmaceutical industry. Endowing the industry with no extra ethical responsibilities beyond those of standard commodity manufacturers, the literature is concerned only with ethical debates insofar as it impacts upon its primary objective of informing effective marketing practices (Parsons 2007).

Literature from other disciplines seems to lie somewhere between these two perspectives, with socio-medical literature written by sociologists representing the closest to the that produced by medical authors; the small body of economics literature aligns more closely with the amoral imperatives of marketing literature. Literature from the field of medical anthropology can be characterised as aligning with marketing literature insofar as it reproduces industry narratives, however its exploration of the moral economy and presentation of critical ideas locates it closer to the middle of the spectrum. Business ethics also has the potential to occupy the middle ground, as illustrated by Buckley (2004). However, as of yet there is still a scarcity of research from this perspective, and therefore more research is required to establish whether such an approach can be successful in mediating such a polarised area of research. Reflecting on the limitations of the current body of academic literature, the following section will discuss alternative forms of literature, specifically mainstream investigative non-fiction.

2.4 Pharmaceuticalisation Literature

When medicalisation is predominantly characterised by pharmaceutical interventions it is referred to as pharmaceuticalisation. The topic of pharmaceuticalisation has been addressed primarily within socio-medical literature. This literature is crucial for understanding both the development of depression and its pharmaceutical treatment. The relationship between medicalisation and pharmaceuticalisation is analogous to a Venn diagram. There is a considerable amount of overlap between the two concepts, but pharmaceuticalisation can exist with no medical diagnosis (particularly with respect to over the counter drugs), and conditions with no pharmaceutical treatment can be medicalised (Abraham 2010). This section examines literature relating to the role of the pharmaceutical industry in medicalisation. This is a topic which has been

addressed by academics from sociology and medicine, as well as by popular nonfiction authors. Both areas of literature will be discussed in turn.

2.4.1 Socio-Medical Literature

Medicine and sociology converge in their discussion of pharmaceutical marketing. Socio-medical literature differs from purely medical literature insofar as it addresses the wider social structures influencing healthcare, as opposed to using the natural sciences to explore the epidemiology and treatment of conditions themselves. Such literature tends to be primarily concerned with patient outcomes (Procyshyn et al. 2004; Perlis et al. 2005; Amaral 2006), and leans towards a utilitarian ethical perspective, although ethical debates are rarely explicitly mentioned (Lexchin et al. 2003). The vast majority of literature examining debates over the ethical status of pharmaceutical marketing comes from this perspective (e.g Healy 2006; Moynihan and Henry 2006; Tiefer 2006; Abraham 2009; Ebeling 2011).

Although it constitutes a cohesive body of literature, there are subtle differences between socio-medical literature written by medical authors and that from sociologists. Consequently, I will firstly examine literature written by medical authors, before moving on to discuss the contributions of sociological authors.

Socio-medical literature written by medical authors adopts a relatively critical stance when discussing pharmaceutical marketing practices (Healy 2006; Moynihan and Henry 2006; Tiefer 2006). Medical authors have been especially critical of the use of PSRs to market directly to prescribers, arguing that such marketing practices serve only to increase prescription costs (Wazana 2000, Morgan et al 2006, Fugh-Berman and Ahari 2007, Ladd et al 2010, Spurling et al 2010).

An equally critical body of literature has also been published about disease mongering and medicalisation. Most notably, a special issue on disease mongering was published by the medical journal Public Library of Science Medicine (PLoS) in 2006 (Moynihan and Henry, 2006). Although each of the papers in the special issue focused on a specific condition, such as sexual dysfunction (Tiefer, 2006), bipolar disorder (Healy, 2006) or restless leg syndrome (Woloshin and Schwartz, 2006), the papers collectively discussed the antecedence and impact of disease mongering. As Amaral (2006: e317) notes, all these conditions 'share the fact that they represent a spectra of symptoms felt by virtually everyone, but which for some people can reach a point at which they become disturbing'. The PLoS collection testifies to the predicament medical practitioners face as the definition, diagnosis, and treatment of diseases continues to blur, a process which is encouraged and exacerbated by an industry which profits from this emergent ambiguity. The authors, many of whom are medical practitioners themselves, express concern for patients whose conditions are medicalised and 'corrected' by pharmaceuticals (Healy 2006, Woloshin and Shwartz 2006, Tiefer 2006). It is important to note that even in cases of severe medicalisation, where the boundaries of a disease classification have blurred heavily into the realms of normal human experience, there still exists a core of individuals who are suffering with severe symptoms and in need of treatment.

The collection addresses the potential negative effects of disease mongering in detail. However, less attention is granted to the possible beneficial outcomes of increased disease awareness. Moreover, the collection presents no insight into the wider business context of disease mongering, in turn, neglecting the wider contextual phenomena which contributes to the issue.

The uniformly critical stance adopted by medical authors has also been subjected to severe criticism. On the subject of PSRs, Rubin (2004) argues that medical authors are often guilty of confirmation and selection biases, by seeking out only negative results. Furthermore, Rubin (2004) states that the potential benefits of such activities are unduly dismissed because the studies, according to the standards of other areas of medical writing, are deemed to be unscientific.

Rubin (2004), a Professor of Economics, provides an in-depth overview of the potential outcomes, and reasons behind such outcomes, which may occur from using PSRs. However, he suggests that prescribing a branded drug as opposed to a generic one

has little impact on a patient's health. Whilst this is true in the immediate sense, at a broader level, high prescription costs can limit the level of treatment available to other patients, especially in the UK where healthcare is funded by the NHS.

As aforementioned, sociologists are also key contributors to the socio-medical body of literature. Whilst socio-medical papers written by sociologists share many commonalities with those written by medical authors, there are a few notable differences. Firstly, whilst medical authors refer to the phenomenon of medicalisation, (Moynihan and Henry 2006, Amaral 2006, etc.) medical sociologist Abraham (2009) takes the argument а step further, describing the phenomenon of 'Pharmaceuticalisation'. Abraham (2009:100) describes this as 'the process by which social, behavioural or bodily conditions are treated or deemed to be in need of treatment, with medical drugs by doctors or patients.' By directly referring to drugs, literature on pharmaceuticalisation holds the pharmaceutical industry to account in a way which literature on medicalisation written by sociologists traditionally has not (Conrad and Schneider 1980, Zola 1972).

Although much of the literature is critical of the pharmaceutical industry's marketing practises, the field is not unanimous in its criticism of Big Pharma. (Morgan 1984) purports that medical journals and pharmaceutical companies have a symbiotic relationship, which, in turn, benefits the journals' practitioner readership. Morgan (1984) suggests that, rather than undermining the quality of a journal's content, the presence of pharmaceutical advertisements serves as a mechanism to maintain quality, arguing that it would be in neither the journal nor the pharmaceutical companies' best interest to present biased information as it would harm the credibility of the journal. In the event of this, Morgan (1984) argues that the principal reason for advertising in academic journals would vanish, and, hence, journals are incentivised to retain and improve credibility through the publication of accurate information to attract and maintain advertising revenues.

An example of a more positive attitude towards pharmaceutical funding is found in a roundtable discussion paper by Donnell et al. (2009), in which all the authors acknowledge a degree of conflict in accepting pharmaceutical funding for continuing

medical education (CME). However, two of the contributors, Donnell and Fox, ultimately conclude that the funding benefits medicine to a greater degree than it hinders it, whilst Backer et al. (2000) suggests that the relationship with the pharmaceutical industry can be symbiotic if managed correctly.

Viewed as a whole, the socio-medical literature provides a nuanced discussion of pharmaceuticalisation and its attendant issues. As one might expect, the literature provides rich insights into the role of healthcare institutions and the experiences of healthcare professionals. However, the literature fails to provide sufficient insights into the role of business and marketing practises in the pharmaceuticalisation process.

2.4.2 Journalistic Literature

As previously outlined, existing academic literature on Big Pharma is not without its limitations. Medical literature must contend with the perception that journal content is biased due to the reliance on pharmaceutical advertising revenues (Morgan 1984). Similarly, marketing literature can suffer from bias due to the interests of its authors and the implied readership. Marketing literature on the pharmaceutical industry is written with the implicit assumption that it is desirable to increase sales, as this is the will of consumers of such research (pharmaceutical companies). Business ethics, however, has yet to produce a cohesive body of literature to contribute to the debate. Furthermore, Dunne et al. (2008) found that academic literature within business and management journals failed to engage with critical political and social debates, which undermines the purpose and relevance of the literature.

As with the broader literature on the ethicality of the pharmaceutical industry, there is also an emergent psychiatry-specific body of critical mainstream literature. Davies' (2013) 'Cracked' is a prime example of investigative, journalistic research that focuses specifically on psychiatry and the pharmaceutical industry. In a similar vein to the present research, Davies dedicates a chapter solely to the marketing of psychoactive drugs and antidepressants. Touching upon some of the issues raised thus far in the literature, such as medicalisation and disease mongering, Davies also criticises the pharmaceutical industry for its marketing methods. Davies goes onto conduct
a whistle-stop tour of the key arguments, including direct-to-consumer marketing, ghost writing, and the use of industry sponsored 'Key Opinion Leaders' (KOLs).

Crazy Like Us (2011) by investigative journalist Ethan Watters presents the argument that America is exporting mental illnesses to the rest of the world. Most relevant to this research is Watters' (2011) examination of the evidence related to the depression epidemic in Japan, subsequent to the condition being promoted there as a 'kokoro no kaze' or 'cold of the soul.' Central to Watters' thesis is the idea that mental health diagnoses are socially mediated and culturally bound. Resultantly, they can be influenced by societal changes, including those initiated by pharmaceutical companies.

Such books serve to enlighten and entertain a lay audience and, although undoubtedly lacking the rigor and depth of analysis of traditional academic research, they are still useful for highlighting potential avenues for future research.

Two of the most critical books of this kind are Joanna Moncrieff's (2007) *The Myth of the Chemical Cure: A Critique of Psychiatric Drug Treatment* and Irving Kirsch's (2009) *The Emperor's New Drugs: Exploding the Antidepressant Myth.* The mythology that each author is referring to is the chemical imbalance theory, which has been promoted by pharmaceutical companies as a cause of depression. However, this fact has not been proven and Kirsch (2009) proposes that the theory depends on the efficacy of antidepressants. In fact, he argues that antidepressants are barely better than a placebo, and, therefore, the theory is incorrect.

Thus far terms such as 'treatment' and 'antidepressant' have been used, however, as Moncrieff (2007) frequently highlights, the use of such loaded terms is far from unproblematic. The way in which drugs prescribed to treat mental health conditions are marketed has been covered extensively by Moncrieff. Moncrieff (2008) is critical of the disease-based view of pharmaceuticals, which conceptualises drugs as treatments or cures targeted at specific conditions or symptoms. Instead Moncrieff proposes a drug-based view of pharmaceuticals, which posits that psychoactive drugs create an 'altered state' rather than returning the body to a state of normalcy (Moncrieff

2008, p. 15). In support of this argument, Moncrieff (2008) notes that psychoactive drugs have the same effect on the brains of healthy volunteers as they do on people diagnosed with mental illnesses. Hence, although it is possible that the altered states generated by such drugs are beneficial for people with mental illness, this largely depends on an individual's drug response and individual preferences. Whilst the drug-based view offers an expedient framework through which to comprehend psychoactive drugs, terms such as antidepressant will continue to be used throughout this research due to the lack of succinct, widely understood alternatives. Furthermore, other terms with etymological baggage, such as 'patient' and 'mental illness' will also be used, again due to a lack of better alternatives (Moncrieff 2008, p. xi).

Whilst Goldacre's *Bad Pharma* provides an overview of the pharmaceutical industry as a whole, Greenburg's (2010) 'Manufacturing Depression' focuses specifically on the role of pharmaceutical marketing in depression. As with 'Bad Pharma', 'Manufacturing Depression' is also shaped, in part, by its author's journalistic experience. Informed by a wide range of academic and non-academic sources, including medical journals, the Old Testament and personal experience, Greenburg (2010) exemplifies how knowledge of the social world is not solely limited to traditional academic sources, an outlook shared by Becker (2007) whose work will be discussed in more detail in the methods chapter.

This research will therefore aim to investigate the expanding UK antidepressant market, by fusing together the socio-medical concepts of medicalisation and pharmaceuticalisation with business concepts and ideas around strategic marketing.

Throughout this section, I have assessed the literature on pharmaceuticalisation, noting that authors from both medicine and sociology have identified that it is driven by the marketing practices of pharmaceutical companies. However, there is hitherto been no contribution to this literature by business or marketing scholars. Furthermore, there is a lack of awareness about the business dimension of pharmaceuticalisation within socio-medical literature. Consequently, there is clear opportunity for this research to introduce a business and marketing dimension to the discussion by

exploring the antidepressant market in the context of the history of pharmaceuticalisation.

2.5 Conclusion

Having presented and discussed academic literature from a rage of disciplines on the ethical status of the marketing of pharmaceuticals, it is apparent that a polarisation exists within extant literature. Socio-medical literature written by medical authors concerns itself entirely with patient welfare to the neglect of the wider business context, as well as being criticised for the level of criticism directed at the pharmaceutical industry (Morgan 1984). Conversely, marketing literature represents only the interests of the pharmaceutical industry, and, as such, fails to engage fully with debates over the ethical status of marketing activities. The discipline of business ethics offers an alternative framework through which to consider the marketing activities of the pharmaceutical industry, by virtue of its acknowledgement of the dual obligations, or more accurately conflicting obligations, facing pharmaceutical companies.

Therefore, this research aims to contribute to the field of business ethics, whilst drawing upon concepts established within other disciplines, such as medicalisation, pharmaceuticalisation, disease mongering/branding and the moral economy. Methodologically, the research draws upon the investigative approach of authors such as Goldacre, Watters and Elliot, as well as a wider body of non-medical investigative literature, which will be discussed in further detail in the following chapter.

3. Methods: An Investigative Social Science of Big Pharma

3.1 Introduction

As discussed in the literature review, an investigative methodology has been applied previously in research into the pharmaceutical industry. However, no research from a business ethics perspective has hitherto utilised this methodology. Therefore, this thesis aims to make a methodological contribution to knowledge in this area, by demonstrating how an investigate methodology can be expedient for business ethics research. Furthermore, the argument will be made that this methodology presents an exciting and dynamic opportunity for academic research more broadly, due to its ability to facilitate the exploration of important unexplored social phenomena.

This chapter begins by delineating the nature of the research and outlining its principal aims. The ontological and epistemological underpinnings of the research will then be established. Given that the methodological approach utilised in this research is relatively novel, close attention will be paid to unpacking investigative social science. Finally, the chapter examines debates pertaining to its usage, before providing a rationale as to why it is a suitable approach for the present research.

<u>3.2 Aims</u>

The aim of this research is to explore the manifold ways in which the pharmaceutical industry has historically marketed, and currently markets, antidepressants.

- Are the increased use of antidepressants and the increase in rates of depression linked, and, if so, how are they linked?
- What methods have been used to market antidepressants, both historically and presently?
- Are pharmaceutical companies using disease mongering and pharmaceuticalisation to promote antidepressants?

 How have the marketing practices of antidepressant manufacturers changed in the face of commercial and political challenges, such as scandals, regulations, and the impending patent precipice for blockbuster antidepressants?

3.3. Epistemology/Ontology

The nature of the social world, and what a social science researcher deems to qualify as knowledge of the social world, directly informs the methodology that one adopts as a researcher. The ontological and epistemological beliefs that underpin this research will now be elucidated.

Epistemological debates are circular in the sense that we turn to knowledge to answer the question of what can or cannot be viewed as knowledge (Johnson and Duberley 2000, p. 4). Whilst the circularity of this pursuit may thus appear trivial, C. Wright Mills noted that 'Awareness of (philosophical debates of knowledge) enables us to become more conscious of our conceptions and our procedures' (1959, p. 120). With this in mind, the following section delineates the epistemological and ontological presuppositions which have directly informed and coloured this research.

The literature review identified that research into the marketing of methods of pharmaceutical companies invariably derives from one of five academic disciplines (sociology, medicine, anthropology, marketing or business ethics), each of which has its own epistemological and ontological conventions.

Work published from a medical perspective tends to be informed by positivist epistemological assumptions, that draw upon the conventions of the natural sciences to establish causation. Marketing literature also has a positivist slant, albeit to a lesser degree than the medical literature. Marketeers, particularly those professionally involved in marketing, are inherently interested in the causal links between inputs and outputs, such as advertising expenditure and sales. Sociological literature tends to be more heterogenous, whilst the contribution from the discipline of business ethics is too scarce to draw out any meaningful inferences about epistemological trends. Overall, much of the literature on pharmaceutical marketing methods tends to come from a more positivist perspective, utilising quantitative methods to establish causation. Whilst positivist research has provided manifold insights into the range of phenomena associated with pharmaceutical marketing methods, certain facets of the phenomena simply cannot be explored from this perspective. This is because, as Brigley notes, positivist research 'fails to address the range of ethical nuances which may be at work in particular contexts' (1995, p. 220).

It is worth noting here that journalism itself is also experiencing epistemological tensions, akin to those which have existed in academia for decades. The emergence of 'data journalism' (Parasie 2014; Coddington 2015) had increased the popularity of positivism in a profession historically characterised by its interpretivist approach. Data journalism refers broadly to the practice of obtaining, analysing, and presenting quantitative data for journalistic purposes (Coddington 2015). Miller (2015) posits that, although data journalism offers many new opportunities for news stories, it is paramount that ethical guidelines are revised and re-established before such practices become commonplace. The sheer quantity and quality of information available via data journalism within society. Miller (2005) fears that perusing data journalism without revisiting ethics could compromise the future sustainability of journalism.

Although, traditionally, the marketing of pharmaceuticals has been approached from a positivist perspective, the present research is informed by more of an interpretivist perspective. Interpretivism is described by Bryman (2012, p. 28) as being 'concerned with the empathic understanding of human action', rather than simply explaining it. More specifically, this research is informed by Giddens' (1984) theory of structuration. Concerned with 'neither the experience of the individual actor nor the existence of any form of societal totality, but by social practices ordered across space and time.' (Giddens 1984, p. 2), structuration provides an expedient framework for considering the links between structures (e.g. 'rules and resources') and social systems (e.g. 'relations between actors or collectives'). When applied to this research, structuration enables the exploration of how depression and its treatments are and have been presented, with a focus on how this presentation is influenced by, and influences, larger structural entities, such as the pharmaceutical industry, medicine, and wider society. Structuration is also favoured due to its dismissal of dualism, such as the kinds of epistemological divisions identified in extant literature. Rather, Giddens proposed that both structure and human agency should be seen as 'mutually constitutive dualities' (Giddens 1984, p. 28). As both structuration and interpretivism acknowledge the embeddedness of the researcher in any research, the social and cultural understandings of the researcher are drawn upon in this research to engage with the meaning presented in the documents and interviews (Giddens 1984; May 1994).

Moreover, as well as existing within a social and cultural context, we also exist within an historical context. In other words, in the process of writing this I am making sense of my decisions by linking them to the ideas of thinkers who have gone before me. Hence, this methods chapter might have been completely different had it been written ten years ago or ten years in the future. History is thus inescapable and imbues every aspect of the research process. Of course, it is the ubiquity of history that causes it to be overlooked. We swim through it like fishes in water. However, Derek Layder makes the case for foregrounding history within social science research:

Since the topic of history traces the changing norms of social behaviour and institutions over time, it is essential to incorporate such concerns in the strategies we use to conduct social research (Layder 1993, p. 6).

For example, whilst a swastika in Germany in 1910 might have been recognised as a symbol of good luck, after its proliferation by the Nazi party, the symbol came to carry an entirely different meaning. Without an understanding of its contextual history the meaning of the symbol cannot be understood. Layder (1993) characterises social reality as interwoven and textured. That is to say, there are multiple levels and dimensions, all of which exist, and can only be understood, within the context of history. Layder uses an example of sexual harassment in the workplace to illustrate his approach:

In order to understand what is involved in a particular instance of sexual harassment at work we have to be aware of how different macro and micro aspects combine to produce the specific instance. Thus, we must be aware of how macro elements like gender division operate in terms of patriarchal power and occupational placement (1993, p. 10).

He argues that macro social forms are interwoven with all layers of social experience, and, as such, are inseparable. Hence, we cannot understand an interaction between two people in isolation from these macro factors, be it an instance of sexual harassment involving two colleagues, a meeting between a pharmaceutical sales representative and a doctor or, indeed, an interview with a psychiatrist conducted by a researcher. In each scenario, we must first understand the history of the context. Further to this, each layer, as demonstrated in Table 1, must be understood in relation to what has come before it.

| | Research element | Research focus |
|---------|-------------------|-----------------------------------|
| History | Contoxt | Macro social forms (e.g. class, |
| | Context | gender, ethnic relations) |
| | | Immediate environment of |
| | | social activity (schools, family, |
| | Setting | factory) |
| | | Dynamics of face-to-face |
| | Situated Activity | interaction |
| | | Biographical experience and |
| | Self | social involvement |

Table 1: Layder's (1993) Research Elements

Layder (1993) places such importance on history that it becomes a method in its own right, which is how it will be considered in this thesis. A scenario such as a pharmaceutical sales representative promoting an antidepressant to a GP is heavily embedded in history: the history of the NHS; the history of the pharmaceutical industry and their relationships; the history of depression as an illness, and its various treatments; how stigma surrounding mental health and pharmaceutical treatments has changed historically. The historical legacy of SSRIs like Prozac is unavoidable when considering the marketing of current antidepressants. Layder's (1993) history-centric methodology is therefore well suited to the study of antidepressant marketing.

Although interpretivist ideas such as structuration (Giddens 1984) and Layder's (1993) modern social theory are expedient approaches through which to approach the topic at hand, it is important to note that these approaches are not a panacea, and, indeed,

these approaches are not without their criticisms. As Kelliher (2011, p. 45) notes, whilst interpretive research is excellent for exploring context in great detail, it is often criticised for its lack of generalisability, validity and reliability. These arguments are usually made about the research methods and designs associated with an interpretive epistemology, and, thus, issues of research generalisability, validity and reliability will be discussed in more detail later in this chapter, along with how an interpretive epistemological framework influences one's methodological choices.

Ontologically, this research is based on the constructionist belief that the social world is deeply interconnected with social phenomena and that meaning is continuously constructed by social actors. Strauss et al. (1963) exemplified how this ontological perspective can inform research by examining the interaction of social entities in a medical setting. The research of Strauss et al. identified a 'negotiated order' (1963, p. 308) between various professions at a psychiatric hospital, observing that 'general understandings' between doctors and nurses were consistently being revised, revoked and established. For the purposes of this research, this ontological perspective underpins the conceptualisation of the organisations involved in the marketing process of antidepressants and depression itself: The Royal College of Psychiatrists (RCPsych), The Royal Collage of General Practitioners, and pharmaceutical companies. Similar to the research of Strauss et al. (1963), these organisations are comprised of individuals who are responsible for defining and negotiating the meaning of depression within their organisation, and, in turn, for wider society.

As discussed in the introduction chapter, this thesis does not evangelically adhere to a single overarching theory. Indeed, Billig (2013) laments the way in which PhD students are indoctrinated into a single theoretical perspective in a manner more motivated by politics than rigour. In contrast, a flexible theoretical approach allows a researcher to better answer a research question by engaging with the data and using theory only where it is useful and insofar as it contributes to understanding and meaning. Consequently, this research engages with ideas from across multiple disciplines, including business management, marketing, medicine, sociology and anthropology. Billig (2013) also purports that, as theoretical approaches evolve within disciplines, they create 'in groups' within which academics can talk to each other and exclude outsiders. This research aspires to speak to multiple disciplines, contributing knowledge to both socio-medical literature and business management. A single, overarching theoretical perspective would thus reduce the utility of this research, rather than increasing it.

3.4 Investigative Social Science

Social scientists are not the sole practitioners of social science. This is an idea discussed in depth by Howard Becker in *Telling About Society*:

My own professional colleagues – sociologists and other social scientists – like to talk as though they have a monopoly on creating such representations [of society], as though the society they produce is the only "real" knowledge about that subject. That's not true.....That kind of talk is just a standard professional power grab. Considering the ways that people who work in other fields – visual artists, novelists, playwrights, photographers, and filmmakers – as well as laypeople represent society will show analytic dimensions and possibilities that social science has often ignored that might otherwise be useful (Becker 2007, p. 6).

Society is studied by people across professions, cultures and classes. Within academia, we invariably elevate the voices of traditional social scientists whilst overlooking those voices from outside of the academy. However, as Becker observes, 'their solutions to standard problems tells us a lot and opens our eyes to possibilities more conventional practice doesn't see' (2007, p. 7). One such profession which can tell us a lot about society, in addition to teaching us new ways of problem-solving, is journalism.

Kutler famously described journalism as 'history with a 5pm deadline' (Kutler 1990 cited in Feldstein 2004). Feldstein reiterated this sentiment suggesting that journalism, and his own academic discipline of oral history, are 'like kissing cousins, with similar family roots and genetic material, they are related but separate; and each has much to teach the other (2004, p. 5).

This belief that journalism and traditional academic disciplines can mutually benefit from a degree of cross-fertilization underpins the methodology of this research: investigative social science. Whilst relatively unexplored in business research, investigative social science is not a new methodological phenomenon. Rather, investigative social science has been discussed in academic literature for more than thirty years under the synonyms of investigative reporting (Levine 1980), investigative research (Ho et al. 2006) and investigative social research (Douglas 1976).

Influenced by the techniques of journalism, investigative social science can be characterised as the naturalistic in-depth exploration of a phenomenon (Ho et al. 2006). Ho et al. note that investigative social science 'is particularly suitable for uncovering, understanding, and reporting social phenomena that may be hidden from, or not easily accessible to observers' (2006, p. 17). It is this feature of investigative social science, that is, its usefulness in exploring otherwise hidden phenomena, that led to it being selected for this research. It was expected that this approach would both fit well with the subject matter, and generate insights unexplored by previous research, particularly within business schools. Examples of research which has successfully utilised this approach includes the work of Scheper-Hughes (Scheper-Hughes 2001,2002,2004), who used an investigative approach to explore organ trafficking.

Through facilitating the exploration of otherwise hidden phenomena (Ho et al. 2006), investigative social science can contribute to the broadening of academic debates. The field of management studies, in particular, has been acknowledged as paying scarce attention to contemporary political and social issues (Dunne et al. 2008). Furthermore, Dunne et al. (2008) found that an overwhelming proportion of management research fails to acknowledge the links between business and wider social phenomena, such as war, violence, migration and race. As Dunne et al. note:

A more recent survey, looking at the top 20 journals in the field of business and management, revealed similar results. As the authors commented, this shows a 'general state of myopia on the part of business and management scholars towards a variety of political issues, even making a virtue out of ignorance (Dunne et al. 2008, p. 217)

It was anticipated that through adopting an investigative approach, informed by structuralism, this research would be able to better explore the practices and impact of businesses on the broader social landscape.

Although there are benefits to using an investigative methodology, previous investigative social scientists have attracted criticism. Douglas' 'Investigative Social Research: Individual and Team Field Research' (1976) was one of the first books to highlight a more conscious overlap between journalism and academic research. Although praised for its entertainment value, critics slated the book on both moral and technical grounds (Gold 1977). Douglas engaged in morally and ethically dubious activity throughout the book, most notably by misleading research participants and ignoring their requests for anonymity. Gold described Douglas' book as 'blood boiling', and urged readers to view the book as 'a curiously inept attempt at satire' (1977, p. 655). Critics suggested that Douglas values the moral status of 'Truth' above all else, and therefore sees 'Truth' as worthy of behaving unethically for. However, by behaving unethically, Douglas sabotaged his research field and made future research impossible. Whilst Douglas' vigilante approach to truth seeking has a Batman-esque appeal, what Hollywood films and comic books do not show is the aftermath of such an approach. Broken windows must be repaired, and broken trust takes even longer to fix. However, none of the critics of Douglas' book argued against the premise of combining investigative reporting and social science, rather it was his execution that was deemed problematic. Above all, both Douglas and his critics remind us of the importance of of good research ethics. The contentious relationship between ethics and investigative research will be discussed in more detail later in this chapter.

3.5 The Limitations of the Journalistic Method

To warrant the usage of such a methodology in business school research, it is important to note why traditional journalism and academic social science research do not make easy bedfellows, even though they are natural allies in many respects. In the literature review, it was argued that journalistic literature can provide interesting and useful insights, however, mainstream journalism also has its limitations. This section begins by establishing what constitutes journalism. The limitations of journalism will then be discussed, along with consideration of how journalism and academia can learn from each other. Consisting of various forms of written, audio and visual content, journalism is a broad concept that is referred to simultaneously as an industry, a profession, a literary genre, and an ideology (Deuze 2005). Journalism occupies an exclusive role in society where it is seen to both act as a lubricant for democracy, and constitute an essential component of freedom of speech (Deuze 2005). As a result, some branches of journalism act as a watchdog for society. This is exemplified by investigative television programs such as BBC's Panorama, which on numerous occasions has drawn attention to cases of malpractice with the intention of stopping the offending individual or organisation (Ware 2006; Chapman 2011; Rowe 2014).

However, there is an argument which suggests that journalism is currently in a state of flux and is less capable of acting as a watchdog in society due to its commercial interests. The book 'The Watchdog That Didn't Bark' explores the role of journalism in the financial crisis, specifically how journalists failed to alert the public ahead of time (Starkman 2014). Furthermore, whether journalism is even qualified to make such judgements about what is in the best interests of society is also subject to contention. There have been occasions in which the watchdog function of journalism has had unintended negative repercussions, such as when Panorama explored the notion of brain death altruistic organ donation falling across Europe (Matesanz 2003).

The privileged status of journalism in society, as well as its limited external regulation, has also raised issues pertaining to ethics. Most notably, the hacking of murdered teenager Milly Dowler's mobile phone in 2002, not to mention the phone hackings of numerous celebrities, exemplified how journalistic privilege can be abused. The ethical issues raised by an investigative methodology will be discussed in greater detail in a later section.

Traditional journalism is also invariably limited by constraints, be it time constraints in the form of deadlines or air-time, or spatial constraints like word-counts and column inches. Moreover, traditional journalism is often encumbered by a responsibility to entertain. The commercialisation of journalism, whether in the form of advertising revenue, subscription fees or a standalone purchase price, has resulted in extensive criticism from some authors. Critics argue that the commercialisation of journalism restrains investigative journalism, which, in turn, has negative implications for democracy (Barnett 2002; Waisbord 2013). Furthermore, journalism, by design, places an emphasis on headlines to the detriment of richness and contextual detail. Contrary to these criticisms, a research paper by Rolland (2006) found that commercial news criteria stimulated the production of high-quality investigative journalism in Norway, which had a positive effect on democracy in the region.

Although the entertainment requirement has not been entirely absent in academic literature, this has diminished over time. Having said this, the recent promotion of the impact agenda encourages academic researchers to consider the marketability of their research findings (Martin 2011). This increased focus and reliance on the responses of readers to one's research will most likely change the focus of academic research to some degree, however the exact nature of this change is hotly debated (Martin 2011; Smith et al. 2011; Gray 2015). However, as Marinetto (2015) notes, academics do have time allocated to pursue research, and possess a skill-set which lends itself to such investigations. Therefore, Marinetto (2015) makes the argument that academics are the perfect candidates to take up the mantel of investigative inquiry.

Commonly referred to as reporting, traditional journalism involves limited analysis, principally dedicated to describing findings to the audience, and perhaps drawing links to previous news stories or potential repercussions. However, when conducting academic research informed by the methodology of investigative journalism, greater scope exists for in-depth analysis. Findings can be explored and presented with reference to existing research, models and theories, thus going beyond simple description by weaving them into the fabric of extant knowledge.

To develop the skills required to put such a methodology into practice, I attended four days of training with the Centre for Investigative Journalism (CIJ) in London. I took part in workshops such as 'Investigating Corruption' with Financial Times correspondent Tom Burgis, 'Analysing Social Media' with citizen journalist Eliot Ward Higgins, 'Interactive Storytelling' with Sandra Gaudenzi from !F Lab, and 'Story-Based Inquiry' with Mark Lee Hunter. In addition to this, I attended two training days at the Cardiff School of Journalism where I shadowed students conducting their own investigations.

The training I engaged in granted me exposure to various kinds of investigative journalism. Investigative social science is a hybrid of social science and journalism, and, as demonstrated by Douglas (1976) and Levine (1980), the combination can vary from case-to-case. Workshops attended at the CIJ enabled me to pick between the various methods and approaches and decide which specific aspects of investigative journalism to incorporate in the research. Whilst I was inspired by the work of every presenter, my own mix of investigative social science is predominantly inspired by the work of the journalist, Mark Lee Hunter. Hunter (2011) uses an investigative approach to write organisational case studies without access. He uses his position as an outsider to his advantage, refusing access arrangements even when they are offered to retain his freedom and independence. Hunter's brand of investigative journalism is known as 'Story-Based Inquiry', and offers a model for analysing data gathered using narrative hypothesis testing. Data is organised in terms of potential narratives which then become hypotheses. These hypotheses are then tested by gathering further data, including data which could nullify the hypothesis. Hunter's (2011) Story-Based Inquiry appealed to me because of its established track record in investigating businesses, as well as the clear, prescriptive nature of the approach.

Whilst academia currently has no way of acquiring the special status which makes certain forms of journalism possible, in the same way that journalism can and is befitting from incorporating aspects of academia, academia can learn from journalism. For example, the journalistic ethos of serving society strongly resonates with C. Wright Mills' (1959) depiction of the public intellectual. Although occasionally accused of being insular and out of step with contemporary issues (Dunne et al. 2008), incorporating journalistic inquiry into academia increases the range of topics available for research, including issues of immediate social consequence. Evidence of how such an approach can allow academics to engage with issues of social significance can be found in Jenkins and Blyton's (2017) investigation into the garment manufacturing industry in India.

This research utilises these ideas to address a topic with broad social relevance which has hitherto been neglected within business research. Moreover, by using an investigative approach, the power imbalance and issues associated with accessing large, and seemingly impermeable, companies are diminished. For example, without the need to negotiate formal access, I do not need to fetter my results to appease industry gatekeepers. I also embrace a journalistic approach in the writing of this thesis. Another area in which journalism excels is in its ability to communicate to a broad audience. In contrast, academic writing is often accused of being overly exclusive, using jargon to alienate those outside of the discipline (Billig 2013). Therefore, in this thesis I try to write in a way which is understandable and free from unnecessary jargon in order to be understood by the legions (couple) of people who will read it. I also occasionally use poor attempts at humour and pop-culture references to slightly increase the readability of this beast.

3.6 Methods

Investigative journalist Bob Woodward (Woodward 2006,2012b,a,2013) notes that there are three 'tracks' to journalistic enquiry. The first, and most commonly used, is interviews. The second, which Woodward argues is currently underused, is documentary research. The final track is a form of casual observation. Woodward (2006) notes that facts can often be calibrated by physically going to locations, an idea which resonates with the present research.

Drawing upon the work of Woodward and informed by the work of academic theorists, this research relies predominantly on interviews and documentary analysis. Woodward's third track was also acknowledged, with findings calibrated along the way through the incorporation of tangible factors such as locations.

There is a dearth of qualitative research on pharmaceutical marketing. Quantitative research has been integral to identifying the impact of traditional marketing activities upon prescription (Wilkes et al. 2000; Gönül et al. 2001; Campo et al. 2006). However, for this research it was decided that qualitative methods would allow for a richer exploration of the power dynamics between social actors involved in the marketing process.

When outlining the epistemological and ontological underpinnings of this research earlier in this chapter, I used the work of Derek Layder (1993) to emphasise the

importance of history. Layder (1993) stressed that history permeates all layers of the research process, which is to say that every aspect of an investigation exists within an historical context. Therefore, research into a phenomenon should include an exploration of the histories of its component parts. Layder (1993) argues that history should be perceived as a method in its own right. In agreeance with this argument, I include findings chapters in this thesis which draw entirely on historical data. This section will outline the methods I used to collect data for this thesis. It begins by outlining the rationale for selecting interviews as the method of data collection, before proceeding to explain who was interviewed and how they were interviewed. Each interview included questions relating to the history of the person and their experiences of the broader landscape of antidepressant marketing. I then go on to describe the portion of my data which most encompasses Layder's (1993) agenda: documents.

3.6.1 Interviews

Abraham and Reed (2002) use an investigative approach to recruit interview participants. The paper focuses on the politics of drug development regulations. Therefore, like this research, the paper examines the pharmaceutical industry and its attendant complex structures. Although they do not explicitly name their approach an investigative methodology, they do describe it as such in the methods section. Referring to participants as 'informants', the authors note that each respondent was selected on the basis of the expertise they were expected to hold. The paper also opts for an investigative lilt when describing the process of fact-checking claims. Similar to Story-Based Inquiry (Hunter 2011), the authors partook in a version of hypothesis testing to identify potential truths. In so doing, Abraham and Reed (2002) testify to how an investigative approach is useful for researching the pharmaceutical industry.

My own approach to conducting interviews was heavily influenced by Abraham and Reed's (2002) research. Respondents were selected for their specialist knowledge and expertise, and, due to the lack of transparency within the industry, this was prioritised above recruiting either a random or representative sample. For this reason, following the example set by Abraham and Reed (2002), I will also refer to participants as informants throughout this thesis. In so doing, I hope to emphasise the value of the

information each person provided me with, in the context of an industry renowned for its secrecy.

Interviews took place with a variety of respondents, including general practitioners, pharmaceutical industry employees, and industry critics. Respondents were given information sheets about the research in advance, and, prior to being interviewed, given time to decide if they wanted to take part in the research. Upon deciding to be interviewed, participants were then asked to sign a consent form. For those respondents who were unable to be interviewed in person, phone or video chat interviews were conducted. In the case of these interviews, consent to record the conversation was a prerequisite. This was explained to respondents in the information sheet and reiterated via email prior to the phone interview. Verbal consent was then obtained and recorded verbally prior to the interview commencing.

Due to the investigative nature of the research, interviews differed in terms of length, tone, and the questions asked, as per the style of interview described by Gilbert (1994, p. 136) as 'non-standardised'. The interviews were thus treated as 'guided conversation(s)' where the objective was 'find out what kinds of things are happening' (or have happened) 'rather than to determine the frequency of predetermined kinds of things that the researcher already believes can happen' (Lofland 1971, p. 76). Whilst the non-standardised technique was mainly selected because of its practicality, it was also selected for its ability to facilitate discovery (Gilbert 1994, p. 136), which is conducive with the investigative approach. Furthermore, this style of interviewing has also been deemed suitable for addressing complicated or sensitive subject matters (Gilbert 1994, p. 138).

All interviews were semi-structured, comprising a list of questions and topics generated ahead of time based on previous findings. However, questions would be freely added or omitted based on respondents' answers.

Mulinari (2013) argues that academics frequently depict the pharmaceutical industry as 'omnipotent controllers of drug markets', thus overlooking the role of other stakeholders. In a 2013 paper, Mulinari presents a more optimistic perspective, exploring how various stakeholders engage in activities which inhibit pharmaceuticalisation. Mulinari's (2013) work exemplifies the complex nature of the wider pharmaceutical marketplace. Comprising multiple stakeholders, the antidepressant market retains this complexity; hence, multiple stakeholder groups have been interviewed for this research.

Pharmaceutical Industry Employees

Eight pharmaceutical industry employees were interviewed for this research. Each of these informants had experience in marketing roles. All informants had worked as Key Account Managers, previously known as PSRs or 'drug reps'. Other roles they worked in included the management and training of sales forces, and developing marketing materials

Healthcare Professionals

In the UK, it is illegal to advertise prescription drugs directly to consumers. Therefore, in most cases, healthcare professionals are the target audience for advertising materials. Healthcare professionals were thus the largest group interviewed. Ten of these informants were contacted using the Disclosure UK database published in June 2016. This database lists the payments made to healthcare providers and organisations in 2015. The database contains over 50 thousand entries and thus relevant healthcare professionals were selected by searching for payments from companies which were working on an antidepressant at that time. Eight of these healthcare professionals had done consultancy work for several different antidepressant manufacturers, and can also be considered as KOLs within the industry.

Medical Public Relations (PR) Agency Professionals

Medical PR agencies play a key role in the marketing of pharmaceuticals, particularly in terms of launching new products. Traditionally, PR agencies liaised with the press to protect, enhance or build their reputation. In the pharmaceutical industry and broader healthcare industry, PR encompasses a broad range of activities, including educational services. For this reason, PR consultancy and healthcare communications can in some cases be interchangeable (Elliot 2004). Furthermore, (Brezis 2008, p. 86)

suggests that public relations agencies can play in important role in the phenomena of disease mongering.

Patient Groups

Patient groups are organisations, often charities, who claim to provide support for patients suffering from a specific condition or type of condition. In this case, patient groups may be depression specific, or more broadly concerned with mental illness. Patient groups are of interest in that they produce information documents, run disease awareness campaigns, and, more generally, provide a key source of information for patients and the public. An ongoing debate around patient groups concerns the status of pharmaceutical funding. Within the depression/mental health cohort of patient groups, there is a split between organisations who do receive pharmaceutical funding and those who refuse such donations. Patient groups proved the most difficult to access for this research, however one interview eventually took place with an informant from a depression charity with a history of collaborating with the pharmaceutical industry.

Industry Commentators

The ethical status of the pharmaceutical industry is a contentious subject which provokes lively public debate. As discussed in the literature review chapter, there is an emergent body of journalistic books commentating on the activities of the pharmaceutical industry. The authors of these publications also engage in debates via blogs, newspapers and public talks. Whilst the authors of these books are professionals whose careers are closely intertwined with their views, there is also a community of more casual commentators. These individuals often run blogs in their spare time, where they comment on industry news as it arises, along with conducting their own online investigations.

Patients

Individuals who have personally experienced depression were not sought out on ethical grounds. However, due to the prevalence of depression, two of the individuals interviewed can be considered as dual-stakeholders. That is to say, as well as belonging to one of the categories above, they also had first-hand experience of depression and its treatments and chose to discuss their experiences in the interviews.

3.6.2 Conducting Interviews

Ultimately, I was able to interview 45 informants, amounting to over 50 hours of recorded data. Informants were selected based on the specialist knowledge they were expected to have, inspired by Abraham and Reed's (2002) selection method. The first interview took place in May 2015, whilst the final interview occurred in December 2016. Over the course of 19 months, I conducted interviews at an approximate rate of one every two weeks. Throughout this time, recruiting and interviewing informants was a full-time job. I used a snowball sampling approach, asking informants for further contacts and recommendations of who to approach next. However, every snowball must have a beginning, and this proved to be extremely difficult and time-consuming. I mined my social circle for contacts, trawled blogs, books and journal articles for names which may be helpful. The most difficult category to find informants from was the charity sector. Lack of full time staff was pointed to as a reason charities could not speak to me. Eventually one informant from a charity agreed to be interviewed after I searched for them on Companies House and contacted them via their company. Fortunately I gathered hundreds of documents on charity activities, including company accounts, leaflets and internal documents which compensated for the lack of interview data from the sector.

Although my informants were diverse in terms of their relationship to the antidepressant marketing process, they tended to share two key characteristics: they were all very intelligent, and very busy. These two factors dominated our pre-interview discussions. Most informants had an intimate relationship with research, having either conducted it themselves, and/or spent their careers critiquing and applying the research of others. Therefore, to gain the trust of these experts I often had to engage in detailed discussions about my methodology, research questions and previous research experience. On three occasions, I sent prospective informant's copies of my Masters dissertation as part of this ongoing discussion. Fortunately, and reassuringly, in each of these cases the individual subsequently consented to being interviewed.

Once the individual agreed to be interviewed, the process of arranging a date and time began. Due to the busy schedules of informants, this was a process that could take months at times. One psychiatrist had to reschedule six times, whilst a GP would only find the time to be interviewed if I were able to pay them. When I explained that I did not have ethical approval to pay informants, they responded that I should approach a pharmaceutical company for money, so that I would be able to pay them. Needless to say, the interview did not go ahead. Typically, there was a month between the individual agreeing to be interviewed and the interview itself taking place. The record was a pharmacist with whom it took nearly nine months to identify a suitable date.

Although finding and negotiating with informants was at times a taxing process, it was also extremely valuable and illuminating. I learned from Becker (2007) that everything tells us something. From these discussions with informants, I learned about their particular relationship with data, their reservations in discussing such a sensitive topic, and gained insight into their day-to-day lives. All of this informed my understanding of what Layder (1993) refers to as macro research elements. Table 2 below provides a brief overview of my interview data, whilst a more comprehensive table about the informants can be found in Appendix A.

| Title | No. |
|--------------------------|-----|
| Charity | 1 |
| Industry Commentator | 3 |
| Medical PR | 5 |
| Pharmaceutical Sales Rep | 8 |
| Healthcare Economist | 1 |
| Neuroscientist | 1 |
| Pharmacist | 8 |
| Psychiatrist | 10 |
| Psychologist | 3 |
| GP | 5 |
| Total | 45 |

Table 2: Table of Informants

3.6.3 Documentary research

Just as Woodward (2006) noted that documentary sources are rarely used to their full capacity in journalism, Atkinson and Coffey (2004, p. 56) 'urge qualitative researchers

to pay proper attention to the forms and functions of such documents'. Documentary sources allow the researcher to examine the past and reflect on contemporary issues (May 1994, p. 1340). Furthermore, The International Consortium of Investigative Journalists (ICIJ) strongly favour documentary research as a key weapon in their investigative armoury (ICIJ 2018). Atkinson and Coffey (2004) purport that documentary research is best conducted from somewhat of an interpretivist epistemological standpoint. Therefore, documentary research was also selected as a method, in part, due to its synergistic relationship with the identified epistemological and ontological standpoint of the research.

Organisations by their very nature generate hordes of documentary evidence, some of which is in the public realm and some of which is private. Marketing actively produces documents, and given that marketing was the focus of this research, documentary research was selected as an essential part of the investigative process.

Documents are not neutral (Atkinson and Coffey 2004). As documents are often intrinsically biased by design, some may argue that they should be dismissed as corrupt data. Atkinson and Coffey (2004, p. 68) note that documents, like all other texts and utterances are 'recipient designed', and, as such, reflect assumptions about the intended audience. With respect to this research, the biased nature of documents is beneficial, and is viewed as a feature as opposed to a bug. The meaning of documents is shaped by many factors, including the status of the author, the historical context, the status of the perceived audience, and the intended function of the document. Such features are therefore being logged and extensively considered, which adds to the richness of the data gathered and subsequent analysis. Again, as noted by Becker (2007), everything tells us something. Hence, while an antidepressant advert may not provide an unbiased depiction of depression, it could still prove extremely helpful in identifying the marketing messages that the company has chosen to promote. Furthermore, attention should also be paid to what documents leave out, because, as (May 1994, p. 138) notes, what is not said can sometimes be more telling than what is. May's (1994) point takes on particular relevance within this research when considering the funding of depression awareness campaigns in Chapter 9.

Documents were gathered throughout the entirety of this project. From very early on in the process, I would spend hours on end sat at my computer trying to understand at the most basic level how the industry operated. By the end of my data collection period in December 2016, I could identify and track down a specific document with the precision of a millennial looking for their partner's ex's private Instagram pictures.

Through shadowing journalists at the Cardiff School of Journalism, I learned how to submit effective Freedom of Information Act (FOIA) requests. The FOIA provides the public with access to information held by public organisations. To increase the likelihood of being successful, a FOIA request must be specific in describing the data requested. In this research, FOIA requests were particularly useful for gaining access to the breakdown of a charity's financial accounts. Such information was not available via the charity commission website, and not published publicly by the charity in question (Depression Alliance (DA); therefore, gaining access to these accounts via a FOIA request allowed me to identify the exact financial value of payments made to the charity by various antidepressant manufacturers.

I gathered historic documents from three physical archives: The Royal College of General Practitioners (RCGP), RCPsych, and Cardiff Central Library. Additionally, I obtained documents from online archives and databases: The Daily Mail, The Guardian/Observer, AdPharm, The Prescription Medicines Code of Practice Authority (PCMPA), Disclosure UK, and the Drug Industry Document Archive (DIDA). Overall, my documentary data gathering resulted in a diverse collection of nearly 500 documents, including media coverage, legal proceedings, journal adverts, leaflets, internal memoranda and emails. These documents were gathered and analysed in tandem with the process of contacting informants and conducting interviews, as outlined by Hunter's (2011) 'open source strategy' which will be discussed in more detail in the following section.

3.7 Issues Related to Good Research Practice

I made a timetable at the very beginning of my PhD journey. A line of boxes plotting a seamless journey from gathering literature, to gaining ethical approval, to writing up and submitting. As alluded to by various self-proclaimed PhD 'survival' guides (a term

which makes light of the poor mental health often experienced by PhD students), progress did not occur along a linear path.

This section presents an honest account of the practical barriers which, at times, called into question whether the research could be completed. The centuries-old Japanese art of Kintsugi involves repairing broken ceramics with precious metals. The golden or silver lines draw deliberate attention to the cracks, whilst, simultaneously, strengthening the artefact. Similarly, in this research the stress points were galvanised, and, ultimately, provided support for the investigative approach of the thesis.

3.7.1 Ethical approval

Gaining ethical approval forms an essential part of any research project involving human participants. As the proposed research involved semi-structured interviews, more specifically interviews with NHS employees, ethical approval was paramount. Due to the intention to interview NHS employees, it was identified early on that there may be cause to apply for NHS ethical approval. The first step in establishing whether NHS ethical approval was required involved determining whether the proposed research was classified as research according to the guidelines of the NHS. One of the criteria for research is that it should be generalisable. Due to the methodology used in this particular study, it was uncertain whether the results would be generalisable, and so further clarification was sought from various staff at the health board, university ethics committee, and the National Institute for Social Care and Health Research (NISCHR).

Once it had been established that the study constituted research, the application process to gain approval from the NHS ethics committee and NHS research and development approval began. The application involved, amongst other things, an 87-page long online form with questions such as 'What is the primary outcome measure for the study?' and other questions with either multiple choice options or numerical tick-boxes. Due to the investigative methodology employed in the research, many of the questions were impossible to answer in an honest and accurate manner. This is because the privileged societal role occupied by journalism means that practices are subject to very little external regulation, as any regulation can be viewed as a threat to freedom of speech.

The friction between journalistic research and ethical approval bodies, particularly health boards, has been extensively documented by Australian researchers (Rolland 2006; Bacon 2007; Davies 2011a,b). These authors emphasise the importance of such research, but lament that bureaucratic organisations are ill-equipped to deal with ethical approval requests from these types of research.

In the case of this research, the investigative, qualitative methodology clashed with the strict, regimented expectations of the NHS process. The NHS deals with applications for clinical trials, research involving human tissue samples, genetics, and vulnerable individuals, and therefore a rigorous ethical approval process is vital and should be commended. However, the NHS is currently missing an ethical approval avenue for investigative, qualitative research.

After many emails, on the advice of the university NHS ethical approval advisor and a representative of the health board, it was noted that if the research did not involve recruiting participants via NHS institutions then a favourable opinion from the NHS ethics committee and NHS research and development approval was not needed. This left only the standard business school ethical approval to be obtained. Although in the case of this research a loophole was identified that meant that the project did not need to go through full NHS ethical approval, this does not negate the fact that the current system is not adequately equipped to deal with applications using an investigative social science methodology.

3.7.2 Access

Originally, efforts were made to gain access to a pharmaceutical company directly to interview key personnel. However, after sending many emails and making many calls, it was established that this may not be possible. Pharmaceutical giants are highly taciturn organisations, and difficulties in gaining access are a common experience of many researchers studying the pharmaceutical industry and other powerful organisations. In this case, the initial setbacks in terms of gaining access to a pharmaceutical company only served to reinforce the investigative methodology of the study. The vast power imbalance between researcher and company, whilst resulting

in many ignored emails, also established the research as a prime area in which to use investigative social science (Ho et al. 2006).

Instead of gaining traditional access via the organisations themselves, I adopted an 'outward-in' approach favoured by Hunter (2011). Rather than beginning my investigation within the metaphorical and physical boundaries of an organisation, I instead began by drawing upon the masses of freely accessible information. I signed up to mailing lists which were popular among various stakeholder groups. I gathered newsletters, press releases and read forum posts. We live in an age where companies are continuously disseminating information via social media platforms, so I followed organisations on Twitter and YouTube. The privilege of conducting my research within Cardiff Business School was that it afforded me access to other sources via paid-for services, such as Lexis-Nexis, Mintel and FAME. When I was initially denied formal access to the organisations I was studying, I was disappointed and unsure as to how to proceed with my investigation. However, Story-Based Inquiry allowed me to focus on the sources I did have access to, rather than those I did not. My investigation ultimately followed what Hunter (2011) refers to as an 'open source strategy', which is outlined in the following diagram taken from the Story-Based Inquiry Manual for Investigative Journalists.

Figure 1: Open Source Strategy (Hunter 2011, p.31)



3.8 Conclusion

This chapter has presented the methodological approach adopted in this research, and the theoretical and practical considerations which supported its selection. An investigative methodology was adopted for this research due to the inherent power imbalance and perceived lack of transparency present in the pharmaceutical industry. Formal access was denied and so an investigative methodology informed by Hunter's (2011) Story-Based Inquiry approach was chosen.

I have outlined how I collected data through conducting interviews and collecting documents. Additionally, through drawing upon the work of Layder (1993), I have emphasised the importance of historical context, and explained why history will form an integral part of the findings chapters. The following chapter is emblematic of this approach, focusing as it does on the history of depression as a diagnosis.

Part 2: The Past: from Melancholia to Depression

4: The Historical Anatomy of Depression

4.1 Introduction

As emphasised by Layder (1993), each intertwined layer of social reality can only be understood in relation to its historical context. Beyond simply serving as a short introduction or a footnote, Layder (1993) considers the analysis of history to be a method in and of itself. It requires data collection and analysis, which, in turn, influences our analysis and understanding of more contemporary research issues. Thus, in accordance with Layder (1993), historical research has been adopted formally as a method in this thesis. Both this chapter and the proceeding one are findings chapters. Rather than simply describing the past, then, primary and secondary sources of historical data have been analysed to explore the relationship between symptoms of low mood and the treatment of such a condition. In doing so, a trend emerges in which the conditions that are related to low mood, are constantly defined by those who claim to be capable of curing it. The problem is thus framed to fit the solution. This finding is revisited throughout the thesis as it permeates all aspects of the research.

This chapter, the first of two historical chapters, focuses on the history of depression as a diagnosis. Prior to the coinage of the term depression, other terms such as spleen, nerves, bile, hypochondriasis, fits, hysteria and being 'down in the dumps' have been used to describe symptoms which we may today associate with depression (Rousseau 2000). Historical figures, such as Vincent Van Gogh (Blumer 2014) and John Keats, are said to have suffered with this condition. Indeed, works such as Van Gogh's *Sorrowing Old Man* (1890) and Keats' 'Ode on Melancholy' (1819) are pointed to as expressions of the artists' inner turmoil. Van Gogh and Keats are just two examples of individuals who experienced depressive symptoms long before Prozac hit the market. The purpose of this chapter is to emphasise that depression has not always been framed as a pharmaceutical issue. In fact, the pharmaceutical industry's involvement in symptoms of low mood is relatively recent and has contributed to the shift towards understanding depression as a medical diagnosis. Moreover, the notion that the these conceptual changes in the diagnosis of depression are a response to the prevailing treatment is not a novel one. Rather, this chapter presents the argument that depression has consistently been framed by those who claim to hold the answer throughout history. This, in turn, helps them to market and sell a treatment.

Diagnoses are 'socially bound' (Ali et al. 2010). Because of this, diagnoses do not remain stable across time or cultures. Due to the socially bound nature of diagnoses, the definition of depression and its predecessors have changed over time. Both this chapter and the following one present a genealogy of depression and trace its historical evolution as occurring in parallel with changes in the treatments available. This chapter presents the history of depression in relation to its treatments prior to the involvement of pharmaceutical companies. Firstly, I delineate the history of conditions, such as melancholia and acedia, which spans across most of the last two millennia, with reference to the role of the church as the primary mode of treatment during this period. Depression in the age of psychoanalysis (early 20th Century) will then be discussed, highlighting how the diagnosis changed in response to the work of psychoanalysts like Freud.

It is important to acknowledge that what follows, with the exception of early Christianity, is primarily a Western-centric history of depression. This is not because Westerners have a monopoly on depression or the symptoms associated with it; rather, throughout history, across the globe there have been interesting and compelling attempts to make sense of these symptoms and experiences. However, due to spatial and time constraints, and for clarity's sake, Western interpretations have been foregrounded in this thesis.

4.2 Pre 19th Century

Accounts of extreme low mood predate the coinage of the term depression. Throughout history, examples exist of individuals for whom persistent low mood had a profoundly negative impact upon their lives. If such individuals were alive today, then they would likely be diagnosed with depression. However, depending on their social and historical context, these figures instead may have received a diagnosis of melancholia or acedia. This section will explore pre 19th Century understandings of low mood. I will examine the diagnoses of melancholia and acedia and illustrate how these reflected the prevailing treatment options available in the era.

4.2.1 1600-1700s: The Church and Marketing the Melancholia Cure

The historical diagnoses which most closely relate to the modern diagnosis of depression are melancholia and acedia. Melancholia is considered by Rousseau (2000) and most authors in the field (e.g. Jackson 2008; Leader 2008b) as the primary precursor to modern depression. A combination of the words melas, meaning black and kholé, meaning bile, the word melancholia came about when the Four Humours theory of medicine rose in popularity around 400 B.C. The Four Humours theory suggested that there were four liquids in the body, and an imbalance of these (which everyone had) led to various conditions, ailments and temperaments. Melancholy was considered one of the four temperaments associated with these humours. As melancholia during this period was defined not by symptoms but by a common cause, (an excess of black bile, which could not actually be proven or measured), melancholia had a wide range of symptoms from the psychological to the physical. Although the condition was broad, Hippocrates noted that in most cases an excess of black bile led to feelings of fear, sadness, despondency, sleeplessness, aversion to food and irritability, all of which are symptoms we would now equate with depression (Jackson 2008; Telles-Correia and Marques 2015).

Each humour could be characterised as either wet or dry or warm or cold. It was believed that an excess of one humour could be treated by exposing oneself to the opposite characteristics of that humour. Thus, if black bile was associated with the qualities of being cold and dry, then the treatment for an excess of black bile could involve spending time somewhere warm and wet, such as relaxing near a lake.

The term melancholia persisted over the following millennia. Due to the socially constructed nature of labels, nuances surrounding the term's usage changed during this time; however, many of the core features of the condition remained the same. The following extract from John Keats' *Ode to Melancholy* (1819) paints a picture of the many symptoms that characterise the condition, which should be familiar to a modern audience as depression:

'No, no, go not to Lethe, neither twist
Wolf's-bane, tight-rooted, for its poisonous wine;
Nor suffer thy pale forehead to be kiss'd
By nightshade, ruby grape of Proserpine;
Make not your rosary of yew-berries,
Nor let the beetle, nor the death-moth be
Your mournful Psyche, nor the downy owl
A partner in your sorrow's mysteries;
For shade to shade will come too drowsily,
And drown the wakeful anguish of the soul.'

In writing this poem, Keats was influenced by the iconic book *Anatomy of Melancholy* by Oxford don and Church of England incumbent, Robert Burton (1857). First published in 1621, but subsequently revised and added to over the course of Burton's lifetime, *Anatomy of Melancholy* is part medical textbook, part self-help book and completely genre defying. Burton drew upon vast readings from contemporary and historical literature, in addition to his own experience of melancholia, to define the condition and its symptoms, causes, and treatment. Moreover, Burton acknowledged that one of the reasons why he wrote, and continued to rewrite the book, was simply to distract himself from his own melancholia. *Anatomy of Melancholy*, as the title suggests, carefully dissects the condition over the course of anywhere from 600 to 2000 pages depending on the edition. Burton's unrelenting quest to understand and explain the condition makes it near impossible to discuss melancholia without referring to his work.

In one passage Burton defines melancholy as follows:

Melancholy, the subject of our present discourse, is either in disposition or in habit. In disposition, is that transitory Melancholy which goes and comes upon every small occasion of sorrow, need, sickness, trouble, fear, grief, passion, or perturbation of the mind, any manner of care, discontent, or thought, which causes anguish, dullness, heaviness and vexation of spirit, any ways opposite to pleasure, mirth, joy, delight, causing forwardness in us, or a dislike. In which equivocal and improper sense, we call him melancholy, that is dull, sad, sour, lumpish, ill-disposed, solitary, any way moved, or displeased. And from these melancholy dispositions no man living is free, no Stoic, none so wise, none so happy, none so patient, so generous, so godly, so divine, that can vindicate himself; so well-composed, but more or less, some time or other, he feels the smart of it. Melancholy in this sense is the character of Mortality... This Melancholy of which we are to treat, is a habit, a serious ailment, a settled humour, as Aurelianus and others call it, not errant, but fixed: and as it was long increasing, so, now being (pleasant or painful) grown to a habit, it will hardly be removed. (1857, p. 93)

From this, we learn that melancholy is the opposite of joy, that it can affect anyone, that it can be transitory or fixed, and that it is a response to grief or a serious ailment. Burton (1857) presents many contradictions throughout the book; for example, sex can cause melancholia in some people but cure it in others, being around other people is important for treating melancholia in some, whereas reading and writing alone can help other people. Rather than detracting from Burton's (1857) characterisation of melancholia, these contradictions deepen the understanding of the reader. What Burton (1857) presents is a condition with a highly individualistic path. There is no single universal panacea presented because there are so many types of melancholia (including one which primarily affects scholars working alone on a large piece of work...), which present differently in different people and whose symptoms are alleviated by different things.

Due to the socially mediated nature of diagnoses, the meaning of the term melancholia has shifted over the course of the two millennia that it has been in usage. However, in both Hippocrates' four humours conceptualisation of melancholia, and Burton's understanding which draws upon several theories, there is an underlying belief that melancholia treatment should be individualised. Burton (1857) notes that more sex may cure one person, whilst causing melancholia in another. The balance of the other three humours, in addition to how the imbalance presented in terms of symptoms, influenced how an excess of black bile should be treated. This idea persisted over the course of the millennia in which melancholia was in common-usage. Melancholia has, to some extent, remained part of the common lexicon (The Smashing Pumpkins' seminal album on 'the human condition of mortal sorrow' (Daher 1998): *Mellon Collie and the Infinite Sadness* was released in 1995). However, the term has largely been

eclipsed today by depression which, as will be explored in the following chapter, has coincided with a less individualised approach to treatment.

The genealogy of human beings points to several ancestors and cousins. Similarly, aspects of modern depression cannot only be seen in the conditions of melancholia and hysteria, but also in acedia (Jackson 1986). Also referred to as accidie, accedie and acedy, early conceptualisations of acedia characterise it as being separate from sin. Instead, it is characterised as more of an occupational hazard for Monks, Hermits and desert dwellers. Whereas melancholia is defined primarily by emotions, acedia also focuses on behaviour. That being said, comparisons between the two have consistently been made, particularly throughout the Middle Ages (Jackson 2008). Acedia is a type of listlessness that can lead to laziness, procrastination and neglect (Altschule 1965). It is also linked to feelings of dejection. Although originally separate from sin, acedia is now also thought of as the predecessor of sloth, one of the seven deadly sins. Furthermore, the condition was understood by some Christians as stemming from possession by the 'noonday demon.'

Literature on acedia is invariably not as expansive as that on melancholia, being almost entirely reserved for Christian texts. Due to the religious embeddedness of acedia, its treatment also came under the jurisdiction of the church. In some instances, particularly within ascetic communities, the 'noonday demon' would need to be exorcised. Within other church communities, those suffering with the condition for extended periods of time would be treated by being ignored. The sufferer's brethren would be commanded not to interact with the sufferer, predicated upon the idea of acedia as being a sin and a personal failing (Jackson 1986).

Treatments for acedia were less diverse and less individualised than those recommended for melancholia. This may be due to acedia being under the sole jurisdiction of large, all-encompassing religious entities. Ritzer's (1983) McDonaldization theory has been used to demonstrate how in modern times the bureaucracy which characterises large corporations can lead to 'irrational homogeneity' in healthcare (Dorsey and Ritzer 2016, p. 16). Such bureaucracy is also

evident in large religious organisations, which may explain the uniformity of melancholia treatment during this time.

4.3 1800s Early Medicalisation

Although it is widely accepted that depression, or depression-like states, can be identified in the works of artists throughout time, relatively little work has been published exploring the history of the condition. Cultural historian George Rousseau (2000) strived to address this gap with his paper 'Depression's forgotten genealogy: notes towards a history of depression'. Rousseau (2000) focuses on the pre-1800 past of depression. Lexically, Rousseau differentiates between the pre-medicalised 'melancholia' and the medicalised term 'depression' which emerged during the 17th and 18th centuries. The border between melancholia and depression, however, is not a clear one. Throughout the 18th century Enlightenment, although depression had become psychologised and medicalised, melancholia still existed, particularly in religious realms where it was associated with satanic possession. Overall, Rousseau (2000) suggests that there are a number of key features of depression's pre-1800 European history. Firstly, the condition developed in relation to the female gender. Rousseau (2000) points to the now debunked and defunct syndrome of 'hysteria', in addition to the work of Kay Redfield Jamison who notes that depression is in line with society's notions of the female gender: passive, hopeless, dependent and sensitive. Secondly, in the 18th Century the condition became medicalised to some extent when it was seen to overlap with male madness. Although Rousseau (2000) also draws attention to the early theories of depression, such as its conceptualisation as a chronic condition from the Renaissance onwards, it is Rousseau's exploration of depression and gender which is most compelling.

There is a growing body of literature exploring the relationship between gender and medicalisation. Authors such as McHugh (2004) argue that, due to the way in which mental illness is categorised, biases are inevitable. Mental illnesses are 'discovered' and defined by the presence of clusters of 'abnormal' symptoms. The very idea of mental illness diagnoses is controversial. In his book *Outsiders*, Becker (2008) argued that deviants are defined by the way society labels them as deviants, rather than by any objective characteristic or behaviour. In terms of mental health diagnoses, then,
this means that diagnoses serve to alienate marginalised groups deemed to be unacceptable by broader society. In the West, psychiatric diagnoses have historically been, and continue to be, categorised by rich white males (Ali et al. 2010). Therefore, it is entirely possible that 'otherness' contributes to the medicalisation of phenomena in a similar vain to Becker's (2008) '*Outsiders'*. The categorisation of homosexuality as a mental illness up until the 1970s (Gray et al. 2015) serves as a powerful example of this bias.

Academics who engage with labelling theory disagree over the extent to which mental illness itself is created by, or in response to, society (Scheff 1971), or whether it is simply a characteristic of normal human variation (Gove 1975). Whilst this debate is interesting, this chapter and the one that follows it are principally concerned with the genealogy of depression as a diagnosis, rather than the factors which contribute to an individual experiencing the symptoms of depression. Irrespective of the underlying condition, mental illness diagnoses themselves are socially constructed. Hacking (1999, p102) provides some nuance to this discussion by differentiating between interactive and indifferent types. Hacking notes that the social construction of some diagnoses could change the underlying condition because of how the person with the condition perceives themselves or is perceived by others – these would be interactive types. This, he argues is the case for attention deficit hyperactivity disorder (ADHD) where institutions treat people differently based on the diagnosis, and could also be the case for depression. Is important to emphasise, that debates surrounding the social construction of diagnoses should not invalidate the suffering of individuals with mental illnesses. A rose by any other name could smell as sweet, and whether you are feeling suicidal because of a chemical imbalance, as an outcome of society telling you to feel that way, or because you fall somewhere on the normal spectrum of human experience, you nevertheless deserve help and sympathy.

4.4 1900s: The Doctor and Marketing the Talking Cure

The 1900s saw a seismic shift in both the understanding of depression and its treatment with the introduction of the ideas of Sigmund Freud. This section explores Freud's impact on the depression treatment market, again positing that it follows an ongoing narrative of depression being framed and defined by those who treat it.

4.4.1 Talking Treatments

A key turning point in the understanding of depression took place in in the late 19th century and early 20th century. Sigmund Freud (1921) introduced the world to psychoanalysis. Freud was a neuropathologist living and working in Vienna where he created the theory and practice of psychoanalysis. Freud proposed that psychiatric problems were a form of coping mechanism, a way through which to deal with underlying problems. These coping mechanisms were believed to be subconscious. Therefore, to treat a patient, the subconscious would need to be explored via talking treatments which addressed the history and childhood experiences of a patient. Famously, Freud theorised that children have unconscious sexual desires for their opposite sex parent, resulting in a hatred for the same-sex parent. Known as the Oedipus complex, Freud suggested that it manifested itself in boys as castration anxiety and girls as penis envy. Through his work creating and developing psychoanalysis, Freud became internationally famous. The term 'Freudian slip' remains in common usage, referring to an unintentional error in speech whereby a person's subconscious feelings are revealed. A 1994 episode of the popular television program 'Friends' featured a musical number about Freud's theory of penis envy:

All you want is a dinkle, what you envy's a schwang' a thing through which you can tinkle, or play with or simply let hang (Friends 1994).

Freud became, and, indeed, remains a pop-culture icon. Prozac, as I will discuss later, has followed a similar trajectory. With psychoanalysis, Freud developed an allencompassing theory of the psyche, which included an explanation and treatment model for symptoms of low mood. Freud perceived of melancholia as being linked to mourning. Whilst mourners are conscious of the loss they are experiencing, those with melancholia are not consciously aware of what they have lost (Freud 1917). In this way, he created a causality which fitted the very treatment he was offering. Freud's treatment focused on uncovering patients' hidden memories to help them deal with them and recover, and, thus, he believed melancholia to be caused by a loss which had not yet been consciously addressed. This moulding of the causality of a condition in the image of the treatment being promoted is echoed later when pharmaceutical companies promote SSRIs to spread the idea that depression is caused by a lack of serotonin in the brain – the so-called, 'chemical imbalance theory'.

Although Freud differed from earlier authors in his beliefs surrounding the cause of melancholia, the symptoms he described seeing in patients bear some resemblance to those listed by Hippocrates in 400 BC:

The patient represents his ego to us as worthless, incapable of any achievement and morally despicable; he reproaches himself, vilifies himself and expects to be cast out and punished. He abases himself before everyone and commiserates with his own relatives for being connected with anyone so unworthy. He is not of the opinion that a change has taken place in him, but extends his self-criticism back over the past; he declares that he was never any better. This picture of a delusion of (mainly moral) inferiority is completed by sleeplessness and refusal to take nourishment, and—what is psychologically very remarkable—by an overcoming of the instinct which compels every living thing to cling to life. (Freud 1917, p. 245)

Freud's approach proved very popular and it was continued and developed by many psychoanalysts who followed him, including Harry Stack Sullivan (Sullivan 1931), Wilhelm Reich (Reich et al. 1946), and Freud's own daughter Anna Freud (Freud 1946). Although each differed in their approach to psychotherapy, they all agreed with the basic premise that psychiatric illnesses were coping strategies to address underlying problems. Right up until the 1980s, a psychoanalytic approach to treating mental illnesses was favoured in both the UK and US (Smith 2014). However, as drug treatments grew in popularity, particularly in the wake of new SSRI treatments, conventions began to shift.

Although psychoanalysis fell out of vogue in the 1980s, a second wave of talking treatments emerged. The most popular of these was Cognitive Behavioural Therapy (CBT). CBT has historically been used as an umbrella term for all kinds of behavioural therapies, some of which date back to the 1950s and 1960s. However, in commonusage it now more typically refers to a specific kind of evidence-based therapy where a person is taught to identify cycles of unhelpful behaviour and break them. The modern incarnation of CBT arose around the same time as SSRIs were being developed. CBT has been found to be more effective than drug treatments for some patients, particularly those with milder forms of depression (Dobson 1989). Further to this, CBT has also proved effective when used in tandem with drug treatments (DeRubeis et al. 1990). However, although CBT has consistently been identified as helpful, and is recommended as the first-line of treatment in the National Institute of Health and Care Excellence (NICE) guidelines, it has never reached the level of success or cultural significance reached by Freud and SSRIs. A psychologist interviewed for this research lamented how competing against drug interventions in some ways reduced the success of CBT:

I suppose it's sort of more complicated. You can't just buy the drug you actually have to train people to deliver it... and compared to the drug companies we don't have the whole marketing arm of it. I guess the drug companies can pay for the education of doctors and things (Fieldwork Interview, Psychologist 1).

Throughout the interview, this psychologist identified manifold reasons as to why CBT has never reached the success one might expect of a treatment deemed to be effective. Most of these reasons centre around CBT being more 'complicated' and less convenient than SSRIs. As will be discussed later, the success of SSRIs was due, in part, to the 'seductive' simplicity of the pill (Zuckerman 2018).

4.5 Conclusion

Diagnoses are socially mediated (Ali et al. 2010) and therefore change over time. Symptoms that we now associate with depression have historically been associated with other conditions, such as acedia, hysteria, and, most notably, melancholia. In each instance, the nature of the condition was partially influenced by the nature of the institution which treated it, which is most notable in the case of acedia and its treatment by the Christian church. As psychological treatments for depression began to emerge, depression itself became validated as a psychiatric diagnosis. As psychoanalysis rose in popularity and cornered the depression market, treatments for depression converged as they did historically for acedia. During the peak powers of psychoanalysis, the industry seemed impossible to usurp. The following chapter explores the fall of psychoanalysis, the rise of pharma, and the impact of this change on depression.

5: The Pharmaceuticalisation of Depression

5.1 Introduction

The previous chapter examined the history of depression treatments apropos the 'four humours' school of medicine, the Christian Church and psychoanalysis. Today, when a person presents to a GP with depressive symptoms they are far more likely to be offered antidepressants than a talking treatment. This chapter traces the journey from there to here. That is, from an era where psychoanalysis appeared 'too big to fail' up until today where antidepressant prescriptions rise year-on-year. Following on from the previous chapter, the concept of pharmaceuticalisation will be used to explore how depression continues to be conceptualised to fit the prevailing treatment.

The chapter is primarily structured around the lifespan of the blockbuster antidepressant, Prozac. Beginning a few decades before Prozac's launch, I will start with the birth of the idea that made such a drug possible: the belief that low mood could be treated by medication. Early pharmacological treatments for depression will then be discussed, before turning attention to the launch of Prozac and other SSRIs. The impact that these drugs and their manufacturers have had on diagnostic criteria will then be analysed.

5.2 1950-80: The Fall of Freud and the First Antidepressants

Freud died in 1939, and although talking treatments remained the norm, in the late 1950s a new branch of medicine was emerging. This new branch of medicine suggested that psychological ailments could be treated, and even cured, via drug therapies.

The antidepressants that were discovered in the late-1950s are commonly split into two categories based on their mode of action: Tricyclic Antidepressants (TCAs) or Monoamine Oxidase Inhibitors (MAOIs) (Healy 2004). The drugs were often poorly tolerated by patients which led to either their discontinuation or lowering of the dosage that had been deemed effective. Common side effects of TCAs included blurry vision, dry mouth, nausea, confusion, emotional blunting, and dizziness (Tueth 1994), whereas MAOI's were known to react dangerously with certain foods (McCabe 1986). Furthermore, both classes were fatal if one overdosed on them. Although they had less than favourable side-effect profiles, both MAOIs and TCAs were found to be effective in treating depression (Thomson et al. 1982; Paykel et al. 1988), and the idea of being able to treat a mood disorder with a pill was a compelling one.

As discussed in the previous chapter, mental health conditions and religious discourse have a rich history, and the development of drug treatments for these conditions testifies to this fact. The birth of modern psychopharmacology was greeted with a religious fervour (Martin 2006). In 1957, Collegium Internationale Neuropsychopharmacologium (CINP), the first international scientific organisation dedicated to psychopharmacology, formed at a meeting in Milan. At the meeting, it was decided that Pope Pius XII should attend the meeting the following year. Accepting the invitation, Pope Pius XII made a speech praising the potential of drugs to treat mental illness. Elsewhere, such drugs were referred to by Frank Ayd Jr. as a 'blessing for mankind' (Healy 1996, p. 84).

Ayd Jr. is considered to be a 'founding father of psychopharmacology in the USA' (Findling cited in Martin 2008). He received the first permit from the Food and Drug Administration (FDA) in America to use chlorpromazine to treat patients with schizophrenia. At the time, such patients would typically be subjected to lobotomies, and so Ayd Jr's. work is believed to have saved many individuals from potentially disabling operations. Building upon his success in treating schizophrenia, he believed other 'brain diseases' would be best treated with medication, and so turned his attention to depression.

Ayd Jr's. (1961) book *Recognising the Depressed Patient* represented a turning point in the conceptualisation of depression and its treatment. Distributed worldwide by pharmaceutical company, Merck, the book helped promote the idea that depression was a medical disease that could be treated with drugs (Healy 1996, p. 99). Prior to sponsoring the launch of the book, Merck acquired the patent for a new TCA amitriptyline. The company therefore had a financial interest in promoting depression as a medical condition requiring pharmaceutical cure (Moncrieff 2008). Ayd Jr's. book would be the first of many to be distributed by pharmaceutical companies to inform healthcare professionals about depression and its treatments (e.g. Tylee et al. 1996). Critics view this practise as disease mongering, which is when a condition is aggressively promoted as an illness, and over-medicalisation, which refers to when the boundaries of a condition are expanded to include healthy individuals (e.g. Moynihan and Henry 2006). The specific message presented by Ayd Jr's. book could also be understood more precisely as pharmaceuticalisation, as the publication promoted the idea that depression was a disease which could benefit from drug treatments (Abraham 2010).

Whilst it can be argued that books such as Ayd Jr's. contributed to medicalisation in a negative way, medicalisation is not always negative (Gray et al. 2015). Therefore, Ayd Jr's. role in medicalisation could potentially be seen as a positive one, drawing attention to depression, reducing stigma and educating the medical community (Greenberg 2010, p. 12). I have found no evidence to suggest that the text was ghost-written, or even that Ayd Jr. himself received funding from a pharmaceutical company prior to the book's publication. Although a dearth of evidence does not necessarily mean that Ayd Jr. was unbiased in his writing of the text, it is possible that he wrote the book with the noble intention of helping patients. His book may then have been cherry-picked by Merck due to its alignment with their marketing objectives. Regardless of his intention, the outcome remains pharmaceuticalisation due to Merck's involvement.

MAOIs and TCAs paved the way for more research into antidepressant medications. Companies were particularly interested in developing an antidepressant with fewer side-effects than MAOIs and TCAs. In 1971, a new compound was synthesised: zelmidine. The compound was part of a novel class of drugs referred to as SSRIs. Due to its different mechanism of action, SSRI zelmidine did not exhibit the problematic side-effects of MAOIs and TCAs. Subsequently, the drug was launched to market in 1982 under the brand name Zelmid. Mulinari (2015) interviewed scientists and managers involved with the development and launch of Astra's drug Zelmid. Mulinari (2015) illustrates how friction between commercial objectives and rigorous science can lead to issues. Standard scientific practice dictated that a drug should undergo testing to discover the optimal dose, and typically patients should be started on a lower dose, before gradually increasing to the optimal dose. However, marketeers liked the idea of starting on a full dose of 200mg on day one, which was likely higher than the optimal dose. The simplicity of a single dose was attractive, and Astra's management saw this as an indicator of the drug's excellence to doctors.

Astra's marketing proved effective, and from its launch in 1982 to 1983 Zelmid was prescribed to over 200,000 patients (Mulinari 2015). Because of Astra's simple but aggressive marketing, the magnitude of Zelmid's success was unprecedented for the time. However, in addition to being the first SSRI to reach the market, Zelmid was also responsible for the first SSRI scandal. In addition to more common side-effects, 1 in every 10,000 patients who took Zelmid developed Guillain–Barré syndrome, which could result in paralysis and left some sufferers permanently unable to walk. In June 1983, the British authorities threatened to withdraw the drug from the market, and in September Astra completely withdrew Zelmid from the market. Mulinari (2015) notes that, whilst the drug was ultimately withdrawn, it nevertheless signalled to other companies about the profitability of the antidepressant sector, thereby paving the way for Prozac. In its short lifespan, Zelmid displayed features of what would become the classic SSRI narrative: from success to scandal.

5.3 1980-2000: The Birth of a Blockbuster

In his paper 'The Shifting Engines of Medicalisation', Conrad (2005) argues that, prior to the 1980s, pharmaceutical companies merely facilitated the medicalisation process, rather than being a primary engine of it. Indeed, the scenario above between Ayd Jr. and Merck would lend support to this idea. However, this soon changed, and pharmaceutical companies went onto become 'major players in medicalisation' (Conrad 2005). Enter Prozac.

In 1989, Prozac (chemical name Fluoxetine) was launched in the UK. Prozac was a member of the new class of drugs known as SSRIs. SSRIs act by increasing the levels of serotonin in the brain. They are therefore based on what is now known as the 'chemical imbalance theory', which, although not scientifically proven, gained a lot of traction in popular culture (Leo and Lacasse 2008).

Prozac itself became a cultural sensation. Frasier (2001) draws upon the Betsky (1997) definition 'magnets of meaning' to argue that Prozac achieved iconic status and became a magnet of meaning during the 1990s. Indeed, the drug rose to fame like no other before it. In the UK, as it is illegal to advertise prescription drugs to the public, we are largely unfamiliar with drug brand names. However, even today Prozac is the most well-known and recognised brand name antidepressant in the UK.

Prozac's iconic cultural status had not been seen before in the pharmaceutical industry. However, its trajectory to fame was typical of its human celebrity counterparts. As Kramer notes, Prozac was: 'renowned, followed by rumours, then notoriety, scandal, and lawsuits, and finally a quiet rehabilitation' (Kramer, 1994: xvi).

Compared to their predecessors, SSRIs were believed to be far safer. This belief, however, was not immediately shared with the public, many of whom were sceptical about the use of drugs to treat depression. The public had a negative perception of psychoactive drugs due to high profile cases of addiction and overdose, such as Judy Garland's death via a barbiturate overdose in 1969. Therefore, across the globe, depression awareness campaigns were conducted to educate the public and healthcare professionals about depression and its treatments. In the UK, this took the form of the Defeat Depression Campaign (See Chapter 9 for more details). This campaign was partially funded by Eli Lilly and, to a lesser extent, SmithKline Beecham (now GlaxoSmithKline (GSK). The precise impact that this funding had on the campaign will be discussed in more detail in a later chapter. However, for now it is simply important to acknowledge that the campaign was a success and is credited with increasing the number of antidepressant prescriptions in the UK in the early 1990s (Paykel 2001). As (Leask 2002) notes, the beginning of the 1990s signalled a cultural shift in how health was perceived. Due to improvements in access to education, and

the growing influence of the media, public expectations of healthcare provision increased. This shift created a culture fertile to the idea presented in the Defeat Depression Campaign that low mood should not be tolerated, but, rather, treated.

5.4. 2000-2017: From Patent Precipice to Public Paranoia

Prescriptions for Prozac and other blockbuster SSRIs, such as Seroxat (paroxetine) and Zoloft (sertraline), continued to rise. However, as we learned from the case of Zelmid, the SSRI narrative is always characterised by success and scandal.

5.4.1 Seroxat Scandal

The SSRI paroxetine was marketed in the UK by SmithKline Beecham (now GlaxoSmithKline), under the brand name 'Seroxat'. In the US, the drug was marketed under the name 'Paxil'. The drug was advertised as the only SSRI safe to use by adolescents (Keller et al. 2001) and, resultantly, was commonly prescribed to teenagers and young adults. However, a pattern seemed to emerge whereby some young people were committing suicide soon after beginning the medication. Critical psychiatrists, such as Healy (Healy 2003), noticed this pattern. However, as suicidality is a symptom of depression, it was difficult to prove that these suicides took place because of the medication as opposed to the depression.

Indeed, if paroxetine was contributing to the suicides of children, then Healy (2003) and fellow critics concluded that it was likely that the clinical trials demonstrating the drug's safety and efficacy in children had been misreported. As part of a growing movement to demand all data from clinical trials, Le Noury et al. (2015) campaigned against GSK to provide access to the original data for the trial known as Study 329. Eventually, GSK granted specific researchers' access to the original data to allow for the study to be reanalysed.

The paper which first published the results of the study in 2001 concluded that paroxetine was safe and efficacious for use in adolescents (Keller et al. 2001). Reanalysis of the study confirmed the researchers' suspicions that the findings had been misreported. The trial participants (depressed teens aged 12-18) had been split into a treatment group and a control group who received a placebo. Upon re-analysing

the data, the researchers found that the participants who had received paroxetine were more likely to self-harm and commit suicide, whilst the drug showed no efficacy in teens. The manufacturers had thus actively hidden data that pointed towards the medication leading to suicide in young people. The decision to hide this data likely led to the death of children and young people, but as with most corporate crimes no prison time was served.

Prozac's iconic image did not protect it from scandal, as the increased risk of suicide was not limited to teens taking paroxetine. Prozac's manufacturer Eli Lilly also hid data pointing to an increased risk of suicide when taking their drug.

Data was also hidden on the likelihood of individuals experiencing withdrawal upon discontinuing SSRIs. Critical blogger Seroxat Secrets (2017) documents the withdrawal journey on their blog. Claims that drugs like Seroxat could cause withdrawal were rebutted. The depression awareness campaign 'The Defeat Depression Campaign' consistently refused to clarify what they meant when they consistently emphasised that antidepressants were not addictive. In response, they merely cited that there is 'no street market for antidepressants' (Crow to Kent, 1992a). As a later chapter will explore in more detail, this campaign was funded by pharmaceutical companies.

The rise of SSRI antidepressants coincided with societal changes about what constituted depression. The companies promoting SSRIs also funded those who wrote the diagnostic criteria for depression (Cosgrove et al. 2006). Feelings which were previously considered part of the normal range of human emotions by DSM-II criteria were now potentially pathological in the DSM-III. Esposito and Perez (2014) highlight the importance of understanding this cycle, whereby conditions are defined by the very people promoting a treatment for it. These definitions are then treated as 'fact' and 'science.' Mental health becomes corporatised which, in turn, leads to the illnesses themselves becoming commodities. Such a system is made possible by the broader social reality which dictates what is normal. In the case of Western countries, such as the UK, this is neoliberalism (Esposito and Perez 2014). Esposito and Perez's (2014) paper on the relationship between neoliberalism and the corporatisation of mental

health argues that the rise of psychotropic medications, such as Prozac, are indicative of wider neoliberal motives:

The individual becomes the focus of attention while the larger market society in which they live is largely ignored. The use of psychotropic drugs, of course, continues to be the primary approach to "treat" individuals by allowing them to overcome their personal challenges and "fit" into the prevailing market order. Fitting into this market society/order typically entails alleviating emotional/mental distress as a way to enhance people's productivity and capacity to consume (Esposito and Perez 2014).

5.4.2 Patent expiration

'A patent is a legal device that grants an inventor market exclusivity over a new invention or medication' (Gupta et al. 2010, p. 2). Patents can be controversial. They can be expensive to maintain and defend and can act as a barrier to innovation. It is for this reason that patenting is decreasing in popularity in some industries. The case of Tesla, the market leader in luxury electric cars, who in 2014 chose to surrender all of their patents to the public is illustrative of this shift (Musk 2014). The company cited a desire to create a 'rapidly evolving technology platform' as one of the key reasons for doing so. Indeed, a tech culture of idea sharing in China is the reason that, contrary to tradition, most teenagers do not care about which brand of hoverboard lies beneath their tree at Christmas time.

However, patents remain at the core of the standard business model in the pharmaceutical industry. This is because the costs associated with the research and development of drugs continues to rise, and thus incentives are required to encourage companies to conduct research and develop new drugs. Patents offer an incentive by providing an opportunity to profit exclusively for a limited period if a new drug reaches the market. It is wholly possible that if patents were abolished in the pharmaceutical industry, then new drugs would not be developed, particularly drugs for rare diseases.

In the pharmaceutical industry, patents protect new drugs from 'copycats' for 20 years. However, as patents must be filed as soon as a new drug is discovered, and it can take years for a drug to be tested and get to market, this, in fact, leaves just over 10 years of exclusive rights in the marketplace. Many of the 'blockbuster' antidepressant drugs, such as Prozac, were released to market in the 1990s and have since come off patent. This means that the chemical compounds can be produced by other companies, which increases market competition and subsequently reduces prices. In 2012, the generic market accounted for 36% of global market share (OBR 2015).

Generic drugs are developed by generic pharmaceutical companies, separate from the larger big brand pharmaceutical companies. The generic drugs have the same active compound as the original branded drug; for example, copycats of Prozac also contain fluoxetine hydrochloride. Although both the branded original and all their generic counterparts have the same active ingredient, they often have different fillers, dyes, coatings, etc. Therefore, all generic drugs are subject to clinical testing to prove their safeness and efficacy.

5.4.3 New Drugs

Although the blockbuster drug, particularly in the case of psychoactive drugs, seems to be a thing of the past, a small number of new drugs for depression have been developed over the past few years. Compared with the SSRI golden age in the 1990s, very few drugs have been released to market since the turn of the century. Furthermore, many drugs that have been in development have failed to ultimately reach the UK market. Vilazodone (brand name Viibryd), is marketed in the US by the pharmaceutical company, Forest Laboratories. However, development of the drug for the UK and wider EU market was abandoned. The private healthcare system in the US means that several drugs which get approved in the US fail to be approved in countries with nationalised healthcare, due to the compounds not offering sufficient 'value for money' to warrant approval. The drug levomilancipran (brand name Fetzima) is another example of this phenomenon, which was approved in the US but had its development discontinued elsewhere.

In a move which could allow companies to avoid cannibalising the market for their existing antidepressants, some companies have researched adjunctive treatments for use with SSRIs. Prozac manufactures Eli Lilly had been researching one such compound up until 2013, when they announced they would be abandoning the

research due to a lack of evidence of its efficacy in a placebo controlled trial (Lilly 2013). Irish pharmaceutical company, Shire, conducted further research into the use of their attention deficit hyperactivity disorder medication, lisdexamfetamine (brand name Vyvanse), as an adjunctive treatment for depression. However, this research was also abandoned due to a lack of sufficient evidence of its efficacy in 2014. The cessation of research into lisdexamfetamine coincided with a complete withdrawal from depression drug development by Shire. As the market has become more crowded and less profitable, several large pharmaceutical companies have withdrawn from the field.

Although in recent years many would-be antidepressants have failed to reach the UK market, three have succeeded: Duloxetine (brand name Cymbalta), Agomelatine (brand name Valdoxan) and Vortioxetine (brand name Brintellix). Due to the tight profit margins in the generic market, they spend less money on marketing, instead competing over price via online catalogues. It is the companies behind these three drugs that have been at the forefront of antidepressant marketing in the UK over the past decade. Therefore, an understanding of these drugs, their features and their position in the market is essential. Each of these drugs has at least one novel feature compared with existing antidepressants. Most notably, each drug differentiates itself from others in the market by claiming to treat a symptom of depression hitherto not targeted by other antidepressants.

Cymbalta

In 2005, Eli Lilly, the manufacturers of Prozac, released a new antidepressant with the chemical name duloxetine and brand name Cymbalta. In the UK, the drug was marketed as a joint venture with German company Boehringer Ingram. The drug is described as working by inhibiting the reuptake of two neurotransmitters: serotonin and norepinephrine. The drug is therefore described as an serotonin norepinephrine reuptake inhibitor (SNRI) rather than an SSRI.

Cymbalta was the first antidepressant to be approved to also treat psychosomatic pain. On Dragons Den or The Apprentice, this would be their unique selling point (USP). Marketing surrounding this medication thus focuses on the link between depression and psychosomatic pain, with slogans like 'Depression Hurts' (Reid 2004). Research conducted by Lilly suggested that the drug was also useful for treating patients with 'milder major depressive disorder', where previously medical guidance had indicated that antidepressants were not necessary (Perahia et al. 2006).

A systematic review published in 2012 by independent research network Cochrane found that Cymbalta was not significantly better than other antidepressants in the treatment of major depression (Cipriani et al. 2012). Furthermore, the authors note 'As for all other new investigational compounds, the potential for overestimation of treatment effect due to sponsorship bias should be borne in mind.' In summary, the authors purport that they found no evidence that Cymbalta is better than other antidepressants; in fact, they found it was worse than some (escitalopram and venlafaxine) and, given that most of the research on duloxetine is funded by the drug manufacturers, it is possible that the drug may be even less effective than their findings suggest.

As Cymbata came to market over a decade ago, it is now off patent and is available in a generic formulation. Despite aggressive marketing, the drug was ultimately unable to replicate the success of Prozac, and, indeed, none of informants reported prescribing the drug even in generic form.

Valdoxan

Manufactured by independent French pharmaceutical company, Servier, Agomelatine (brand name Valdoxan) was released to the UK market in 2009. Unlike SSRIs, Agomelatine is similar in structure to the sleep regulating hormone melatonin, and for that reason is described as a melanotonic antidepressant. As the drug acts on the melenatonic system, it is claimed to regulate sleep patterns or 'circadian rhythms'. Prior to the launch of Valdoxan no other antidepressant claimed to regulate sleep in this way, and, hence, this became the drug's USP. In addition to regulating sleep, the drug has also been described as having a favourable side-effect profile (Rouillon 2006). Specifically, the drug does not have the sexual side-effects which often cause patients on SSRIs to discontinue treatment. Although the drug does not have sexual side-effect: liver damage

(Freiesleben and Furczyk 2015). Resultantly, patients taking the drug cannot drink at all. This is especially problematic due to the increased propensity of individuals with depression to consume alcohol. In addition to abstaining from alcohol, individuals taking Valdoxan must undergo frequent blood tests to monitor liver function.

Valdoxan is still on patent in the UK and Servier still have sole marketing rights over the compound. However, an industry informant stated that Servier have stopped marketing the drug as the blood tests are 'a ball-ache' for GPs (Fieldwork Interview, Rep 3). Although the drug is no longer being marketed in the UK, it is allegedly successful in private practice: 'it's the favourite antidepressant in all of private practice because it has almost no side-effects at all, so there are all sorts of things that are unwritten but we all know about' (Fieldwork Interview, Psychiatrist 6).

Brintellex

In November 2015, NICE published guidance for prescribers to include Vortioxetine (brand name Brintellex) as an option in the treatment of depression. Brintellex is an atypical antidepressant, and has been described in a paper sponsored by its manufacturer, Lundbeck, as 'a novel antidepressant with multimodal activity' (Sanchez et al. 2015). By this, the authors mean that the drug increases multiple neurotransmitters: serotonin, noradrenaline, dopamine acetylcholine, histamine and glutamate. The USP of this drug is that it is the first antidepressant which also claims to treat cognitive dysfunction.

As Brintellex is still on patent, it is thus more expensive than drugs for which there is a generic alternative. Currently, NICE guidelines only suggest offering Vortioxetine to individuals who are experiencing treatment resistant depression, and have thus far not responded to at least two other forms of antidepressants (NICE 2015). Brintellex is unlikely to ever match the success of Prozac, and it would appear that the era of blockbuster antidepressants is over. However, antidepressants remain the most dominant treatment for depression.

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5.5 Conclusion

Due to the socially bound nature of psychological diagnoses (Ali et al. 2010), the definition and understanding of depression has changed over time. These changes consistently correspond with changes to the way in which depression is treated. Historically, the market for depression treatment was initially dominated by religious groups, later by psychoanalysts, and then by pharmaceutical companies. As Healy (1996) notes, someone has always had a vested interest in the way depression is treated, which, in turn, means that they have also had a vested interest in how depression being framed by those promoting a treatment. The pharmaceutical industry has dominated the market for depression treatment for decades now. However, with patents expiring and new challengers emerging, the industry has faced several challenges in its attempts to replicate its earlier success.

This section has traced the historical evolution of depression and its treatments. In the following chapters, I examine in greater detail how Big Pharma companies marketed a chemical solution to depression. This story takes us through the role of not only PSRs, hired from within the industry, but also outsiders such as healthcare professionals and charities. It demonstrates how the marketing of antidepressants has evolved beyond increasing demand via pharmaceuticalisation or disease mongering. Instead, I show that antidepressant marketing activities are influenced by a motivation to change the broader landscape of society to fit their objectives. In other words, medicalisation is not enough for understanding the commercial strategy of Big Pharma – it has a political role. This thesis concludes by considering the future of antidepressants, thinking about the respective challenges and opportunities for pharmaceutical companies promoting treatments for depression. The following section explores the next step in this larger narrative. It looks behind the veil of the industry that, depending on your perspective, produces treatments or illnesses.

Part 3: 'Big Pharma' and the Blues Business

6: The Rise of Big Pharma

6.1 Introduction

The term antidepressant itself is clever branding. The word suggests that the drugs specifically target depression, and that depression is a singular identifiable thing that the drugs can then combat. If antibiotics kill bacteria, then antidepressants kill depression? Antidepressants are chemical compounds with an array of effects, some of which may sometimes be helpful in treating depression in some people. Moncrieff and Cohen (2006) refer to this as the 'drug-centred' view of medicine, as opposed to the disease-centred view. Moncrieff and Cohen's (2006) drug-centred approach argues that we should acknowledge that there is no such thing as side-effects. Rather, there are simply effects, some of which are desirable and intended, and some of which that are not.

Antidepressants (a term I will continue to use for ease of communication) are psychoactive drugs. Antidepressant manufacturers are also the generators of compounds which are used to treat other conditions. They are large pharmaceutical companies with rich histories long predating Prozac. Therefore, to make sense of the antidepressant market and the various activities of its players, like many of the films in the popular Marvel Cinematic Universe, we must first establish the industry's 'origin story'. Exploring this origin story is especially important because, as discussed in the methods chapter (and as reiterated throughout this thesis), history permeates every layer of the research subject. Antidepressants are inseparable from the industry which makes them. The perception of antidepressants has thus been influenced by the reputation of Big Pharma, while, in turn, antidepressants have been something of a lightning rod for issues within the industry. Furthermore, every marketing interaction between a pharmaceutical representative and a healthcare professional is defined by the accident of history that caused drug development to take place outside of the NHS.

This chapter presents an overview of the pharmaceutical industry, which is crucial for situating and understanding how depression has become a business concern for Big

Pharma. It begins by drawing upon the work of Malerba and Orsenigo (2002), whose work plots the history of the pharmaceutical industry from its pre-war beginnings, through to the golden age which saw the discovery of antidepressants. I then proceed to outline its current state, which has led to Malerba and Orsenigo (2002) predicting its demise. Exploring the history of the industry, it becomes apparent that the reputation of Big Pharma has changed drastically over time. This issue will be presented and explored through the lens of scandal. Given that this reputation has influenced how the industry regulates itself, the chapter concludes by examining in detail the structure of self-regulation in the industry, and how it has changed in response to scandal.

6.2 History

Malerba and Orsenigo have written extensively on the history of the pharmaceutical industry. Their 2002 paper provides an especially detailed historical typology of the pharmaceutical industry. Consequently, their work is drawn upon in this chapter to analyse the historical development of Big Pharma. More specifically, their work is used to understand and periodise the development of Big Pharma and its involvement in antidepressants. Periodisation is the process of categorising the past into discrete, defined blocks of time to facilitate the study and analyses of history. In their 2002 paper, Malerba and Orsenigo split the history of the industry into three eras: early history, the random screening period, and the advent of science. In 2015, they add 'the winter of discontent?' to their typology. This chapter is therefore structured similarly, using and developing Malerba and Orsenigo's (2002; 2015) periodization to facilitate the study and analysis of Big Pharma's origin story, as well as its movement into the depression treatment market. Moreover, I adopt this general historical typology to consider and understand the specific historical origins of the antidepressant market and its domination by private corporations.

6.2.1 Early History: War - What is it Good for?

The pharmaceutical industry first emerged out of the German and Swiss synthetic dye industries during the mid-nineteenth century (Malerba and Orsenigo 2002). Drawing upon their knowledge of organic chemistry, companies such as Ciba, Sandoz, Bayer and Hoechst diversified into the manufacturing of drugs. Malerba and Orsenigo (2002) note that it was not until the later years of the 19th century that the industry began to develop in the UK and US. However, rather than being subsidiaries of larger chemical companies, British and American companies were specialist pharmaceutical companies. Firms such as Wyeth, Eli Lilly, Pfizer, Waner-Lambert and Burroughs-Wellcome all dealt specifically with pharmaceuticals.

Periods of national conflict and war are frequently cited as periods of innovation, and, historically, this has been no different within the pharmaceutical industry. WWII generated increased demand for mass-produced antibiotics, which, in turn, led to the commercialisation of Penicillin that Orsenigo and Malerba (2002:4) identify as 'a watershed in the industry's development'. This is because the industry now had a model for producing medication quickly and efficiently in large quantities. Post war developments led to the growth and expansion of pharmaceutical companies, such as Glaxo Laboratories (a predecessor to Seroxat manufacturers, GSK) and future Prozac manufacturer, Eli Lilly.

Whilst war certainly helped the development of Big Pharma, it was what happened after the war that was crucial for its growth and expansion. A key moment in the history of the pharmaceutical industry in the UK was the creation of the NHS in 1948. Prior to the NHS, healthcare was paid for differently by different groups of people. Although some working men had access to health insurance, this often failed to cover the cost of drugs and was only available to those who paid national insurance, thus invariably excluding women and children. For the most part, medication was paid for by patients out of their own pockets. Patients are price sensitive consumers (Strombom et al. 2002), something that has been routinely demonstrated in recent years when uninsured Americans forgo necessary but expensive medical treatment due to cost. Therefore, patients often went without drug treatment if they could not afford it, thus reducing demand for medications. The NHS, for the first time, created a chain where the person receiving the drug treatment was not the person paying for it. Aneurin Bevan founded the NHS on three guiding principles: 'that it meets the needs of everyone, that it be free at the point of delivery', and 'that it be based on clinical need, not ability to pay' (NHS.uk 2018). Resultantly, demand for medications increased, and by 1951 prescriptions had more than trebled (Abraham 2009).

However, the pharmaceutical industry managed to remain private, thus leaving the UK with a nationalised health service but a private pharmaceutical industry. Abraham explores the issues associated with this dichotomy, observing that the modern pharmaceutical industry was already well underway before the health service became nationalised (2009, p. 936). The case for partial public ownership of the pharmaceutical industry was made by Harold Wilson prior to his success in the 1974 election. However, the inertia already inherent in the pharmaceutical juggernaut prior to nationalisation, goes some way to explaining why, despite criticisms, it remained entirely private.

Leask (2002) points out that the set-up of a private pharmaceutical market, working with and for a nationalised health service, had a huge impact on the nature of the pharmaceutical market. Healthcare was predominantly led by GPs who operated as individual practitioners. Negotiations during the formation of the NHS led to GP's becoming contractors for the NHS rather than employees. This legislative relic remains in effect and has manifold repercussions which will be discussed in Chapter 8. For the pharmaceutical market at this time, the power held by GPs meant that the Health Authority had little to no influence over how GP practices were run.

During this time, Leask (2002) notes that there was little price sensitivity within the market. Healthcare professionals were prescribing medicines for patients with little awareness of the cost of the drug, as this issue was simply not relevant for the doctor or the patient (as neither would be footing the bill directly). This lack of price sensitivity allowed pharmaceutical companies to increase profit margins. Large companies were, in turn, able to dominate communication with customers via 'muscle marketing' (Leask 2002). Large companies hired large, focused sales forces who targeted individual practitioners for one-to-one conversations about the features and benefits of their company's drugs. This signalled the birth of a sales technique which would later contribute to the success of SSRIs.

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6.2.2 Random Screening

The period from the end of WWII to the mid-1970s is referred to by Malerba and Orsenigo (2002, p. 4) as the 'Random Screening' period, as well as 'the golden age of the pharmaceutical industry'. The commercialisation of penicillin demonstrated the profitability of drug development. Prior to this era, very few diseases had effective cures. There was therefore an 'open field' for companies to develop and market new drugs in the therapeutic domain with very little competition. Malerba and Orsenigo describe the environment at this time as 'target rich' (2002, p. 4), however scientific knowledge at the time was less developed. A 'random screening' approach was therefore adopted by companies to investigate 'libraries' of compounds via test tube experiments and animal testing. This process relied primarily on chance, and, indeed, only one in every 5,000 compounds ultimately reached the market (2002, p. 5).

Although far from perfect, the screening process was successful and led to the discovery of several hundred new chemical entities throughout the 1950s and 1960s. Furthermore, the screening capabilities developed by companies were complex and difficult to imitate. This created a barrier for new companies entering the marketplace and is a key reason why the market is still dominated by early entrants to the pharmaceutical industry, which are described by Malerba and Orsenigo (2002) as the industry's 'oligopolistic core'.

Moreover, as noted by Healy (2012b), there were changes to the patent system during this time which facilitated profitability. Process patents had been the norm in Europe prior to the 1960s. This meant that pharmaceutical companies were awarded patents based on the processes used to create the drug. If other companies were able to create the same compound using a different process, they would thus not be infringing on the patent. Innovation was therefore encouraged, and companies could compete against patents to find a cheaper way of creating a useful compound. In the early 1960s, however, European countries switched to the US system of product patents, which protect the chemical compound regardless of how it was made. This transition reduced the incentive to innovate and discover a cheaper way of creating a drug. Consequently, this change in patent procedure increased the profitability of new drugs by reducing competition. Furthermore, Goldacre (2012) argues that this patent system

encouraged a greater emphasis on marketing compared to research and development. In doing so, product patents paved the way for blockbuster drugs like Prozac.

6.2.3 The Advent of Science

The third period in the industry's history is referred to by Malerba and Orsenigo as 'The Advent of Science' (2002, p. 6). This era began in the 1970s, and when Malerba and Orsenigo published their paper in 2002, they considered themselves to be still living in 'The Advent of Science'. This era is characterised by advances in scientific knowledge which allowed companies to improve their screening process, and more efficiently identify potentially useful compounds. Moreover, understanding of diseases and drug mechanisms improved, further streamlining the drug discovery process. Knowledge of molecular and DNA levels led to the development of new biotechnological firms (NBFs), which, in turn, saw the advent of drugs such as insulin.

Drug discovery and development became increasingly dependent on a wide, diverse and fragmented range of knowledge. Therefore, NBFs and more established pharmaceutical companies frequently had to collaborate to succeed. A 'network of collaboration' thus evolved during this time between pharmaceutical companies, NBFs and universities.

The Advent of Science also led to the first blockbuster antidepressants: SSRIs. These drugs worked by altering the level of the neurotransmitter, serotonin. Because of this, SSRIs were sometimes described as being analogous to insulin, and so the chemical imbalance theory of depression was born. The marketing developments established during 'Early History' and the patent developments in 'Random Screening' provided antidepressant manufacturers with the perfect tools to create incredibly profitable branded medicines.

6.2.4 Regulation Burden

In their 2015 paper on the evolution of the industry, Malerba and Orsenigo updated their historical account by adding a fourth era entitled the 'Winter of discontent?', which covers the period between 2000-2010. The authors go so far as to question whether

we may be witnessing the demise of Big Pharma. This is down to the fact that advancements in knowledge and technology have increased the cost of bringing a drug to market. Malerba and Orsenigo (2015) highlight that roughly the same number of new chemical entities were approved by the FDA in the early 1980s as the early 2000s. However, the cost of research and development over this time increased thirtyfold. Regulation has been blamed for this decrease in productivity. However, Malerba and Orsenigo (2015) note that, as well as regulation, there has also been success in terms of shortening development times. Moreover, the 'open field' of 'The Golden Age' has become occupied by a suite of products against which new medications must compete. The history of the coal industry provides us with a useful comparison for understanding this trend. What is close to the surface and most easily accessible is excavated first, whereas as time progresses more money and energy is required to access the remnants.

Further to this, the collaborative sentiment of 'The Advent of Science' evolved into a deepening division of labour during the 'Winter of Discontent?'. Large pharmaceutical companies outsource research and development to specialised biotech firms. Malerba and Orsenigo (2015) argue that this evolution has resulted in large pharmaceutical companies being at risk of losing their capacity to innovate, having instead now become simply 'marketing-based organisations'. This acknowledgement that marketing has become the core competency of these organisations, rather than research and development, further supports the underlying premise of this thesis. Before we can understand the ethics of the pharmaceutical industry, however, their approach to marketing must first be examined.

6.3 Pharma Scandals

Malerba and Orsenigo (2015) note that, throughout the 1990s, the pharmaceutical industry enjoyed 'a remarkable reputation in the eyes of the markets, policymakers and the people at large'. Macaulay Culkin had a similarly glowing reputation during this period. However, just as scandal almost always accompanies the fall of child stars in the form of narcotics convictions or jail-time, so too does it plague Big Pharma (or the pharmaceutical industry) and their blockbuster drugs.

Public trust in the pharmaceutical industry has been eroded by scandal (Lofstedt and Way 2016). How did the industry fall from being a political darling to shorthand for corruption and mistrust? The answer: scandal after scandal. This section starts by looking at broader industry scandals across the respective drug classes, before proceeding to discuss the mechanisms which contribute to such scandals .

6.3.1 Death by dangerous drugging

The previous chapter looked in-depth at specific antidepressant scandals, and thus I will not discuss them at length in this chapter. However, Hernandez et al. (2014) posit that the Seroxat Scandal was the key turning point in terms of the public losing trust in the industry. Their paper exemplifies how the controversy surrounding antidepressants has acted as a lightning rod for a wider discussion of industry ethics. To quickly recap, GSK hid trial data which demonstrated that Seroxat increased the suicidality of young people. Rather than publish this data, they promoted it as safe for use in children, therefore likely contributing to the deaths of young people who would otherwise be alive today. Additionally, some patients taking Seroxat became dependant on the drug and found it very difficult to come off. However, GSK maintained that the drug was not addictive. The Seroxat Scandal went on to become part of the largest pharmaceutical industry settlement in history of \$3 billion.

However, it is important to note that the pharmaceutical industry has experienced scandals across multiple drug classes. The non-steroidal anti-inflammatory drug (NSAID), Rofecoxib (brand names Vioxx, Ceoxx and Ceeoxx), was considered a success for the pharmaceutical company, Merck & Co. Over 80 million individuals worldwide were prescribed the drug between 1999 and 2004. However, in 2004 the drug was removed from the market as it was shown that the drug resulted in a five-fold increase in the risk of heart attack compared with naproxen (another popular NSAID). Again, the data on the side-effect of the drug was hidden, thus resulting in tens of thousands of avoidable heart attacks.

Heroin addiction has soared in the US in recent years along with HIV infections. This epidemic has been the subject of multiple documentaries pointing towards the rise in use of opiate painkillers, such as oxycodone (brand name OxyContin), as a

contributing factor. Oxycodone was originally advertised by its manufacturers, Purdue Pharma, as less likely to be abused than other narcotics. A lawsuit settlement in 2007 found Purdue guilty of misbranding, because they did not have enough evidence to support their marketing claim (Meier 2007). The company were ordered to pay \$600 million and three executives, including the president, pled guilty and agreed to pay \$34.5 million in fines. During this period in which the company were actively advertising OxyContin as a lower risk, they earned \$2.8 billion in revenue.

Investigative podcast 'Embedded' (McEvers 2016) followed the story of a nurse and girl scout leader who ended up living in a drug den after becoming addicted to another opiate painkiller, oxymorphone (brand name Opana ER). She was originally prescribed the drug for a back injury she sustained whilst helping a patient. Opana ER was removed from the US market in June 2017 at the request of the FDA, because it was being abused by those taking it. The opioid crisis in America has reached such critical proportions that even problematic President Donald Trump has pledged to declare the crisis a national emergency (whether he will, of course, is yet to be seen) (Crow 2017).

The US opioid crisis has received a lot of media coverage in recent years. Whilst the UK has not experienced an epidemic of US proportions, pharmaceutical companies have still been accused of contributing towards the over-prescription of such drugs. Stannard (2012) notes that prior to 2003 pain specialists had a very liberal approach to prescribing opioid painkillers. They held the view that pain was the enemy and opioid painkillers were their best weapon in this battle. Their beliefs were 'facilitated by a tide of educational initiatives sponsored by pharmaceutical companies selling the next best thing' (Stannard 2012, p. 7).

6.3.2 Not Just Bad Apples but a Rotten Orchard?

These scandals are not isolated cases; rather, they have drawn attention to underlying corrupt practices which facilitate such scandalous outcomes. What do the *Goosebumps* series of books, Sarah Palin's memoir *Going Rogue* and the article publishing the results of rofecoxib clinical trials have in common? They were all allegedly ghost-written. R.L. Stein maintains that he wrote every book in the

Goosebumps series, and, indeed, there is little solid evidence to suggest that he did not, Palin's ghost-writer's diary was leaked by Salon, whilst an analysis of litigation documents by Ross et al. (2008) found that articles were ghost-written by Merck as opposed to the high-profile academics who received authorship credits. Ghost-writing is fairly commonplace in the industry. Indeed, one informant from a PR company I interviewed spoke candidly about providing a writing service for pharmaceutical companies. This involved matching companies up with authors who would write up their trials to a flattering and publishable standard, without being listed as an author.

Scandals such as these have led to an erosion of trust in the industry. Both the public and healthcare professionals have become more sceptical towards the pharmaceutical industry as a whole. Goldacre's (2012) 'Bad Pharma' further solidified this widespread distrust of the industry. Goldacre is a GP who began writing the column 'Bad Science' for The Guardian in 2003. The column exposed examples of how poor science was used to manipulate people and proved extremely popular. In 2008, Goldacre published the book 'Bad Science' followed by 'Bad Pharma' in 2012. Goldacre summarises the thesis of 'Bad Pharma' as follows:

Drugs are tested by the people who manufacture them... ...unsurprisingly, these trials tend to produce results that favour the manufacturer.... ...we only ever see a distorted picture of any drug's true effects... ...This distorted evidence is then communicated and applied in a distorted fashion. In their forty years of practice after leaving medical school, doctors hear about what works through ad hoc oral traditions, from sales reps, colleagues or journals. But those colleagues can be in the pay of drug companies – often undisclosed – and the journals are too. And so are the patient groups. And finally, academic papers, which everyone thinks of as objective, are often covertly planned and written by people who work directly for the companies, without disclosure (Goldacre 2012, p. xi).

'Big Pharma' was a commercial and critical success and remains popular today. 'Bad Pharma' ended with a call to action for healthcare professionals, academics, industry employees and the public. Goldacre subsequently used the success of the book as a springboard for the activist campaign 'AllTrials.' Echoing the sentiment of the final chapter of Goldacre's book, the campaign offers resources on how to 'fix medicine.' 'Bad Pharma' was, however, less popular within the industry. The Association of the British Pharmaceutical Industry (APBI) issued a statement in response to the book's

publication, stating that it highlights historic issues which are no longer a problem; indeed, one informant I spoke to accused Goldacre of scaremongering.

6.4 Self(ish) Regulation

The existence of such scandals begs the question: how is the industry regulated? We might expect companies which hold our lives in their hands to be subject to intense regulation. However, interestingly, the pharmaceutical industry in the UK entirely funds its own regulation, a regulatory style which has remained unchanged even in the wake of such aforesaid scandals.

Government regulation is conducted by the Medicines and Healthcare Products Regulatory Authority (MHRA). The MHRA is an executive agency formed by the government to ensure the safety of medications and medical devices. They are responsible for activities such as regulating clinical trials, granting market authorisation for new medicines, and conducting post-marketing surveillance to monitor the sideeffects of medicines already on the market.

As the MHRA is government run, it should function independently and prioritise the needs of the public. However, the MHRA is not funded by tax-payers. Instead, it is funded by fees administered to pharmaceutical companies. This funding model has led to accusations that the MHRA is biased and prioritises the interests of pharmaceutical companies over the safety of the public. Moreover, the current Chief Executive of the agency, Dr Ian Hudson, previously worked for GSK. Whether or not a history of working in the pharmaceutical industry should exclude someone from such a role is debateable, as experience in monitoring the safety of medications for a company could be valuable for the role. However, notably, Hudson defended GSK as an expert witness in a trial where he testified that he had seen no evidence to suggest that Seroxat had caused any person worldwide to commit suicide (Healy 2012a).

The ABPI is a trade association comprising pharmaceutical companies. They introduced their first voluntary code of practice in 1958 (Herxheimer and Collier 1990). As a trade association, the ABPI both represents and comprises pharmaceutical companies operating within the UK. Due to the status of the ABPI as a trade

association, criticisms have been made regarding the phenomenon of 'regulatory capture'. Regulatory capture occurs when the functions of a regulator are corrupted by sharing a common interest with the subjects of regulation. In the case of the pharmaceutical industry, by being both the enforcers and subjects of regulation, it is argued that regulation cannot be truly enforced (Herxheimer and Collier 1990). This issue is compounded by the lack of historic transparency that characterises the industry, which Abraham (2008) describes as 'highly secretive.

The core component of the regulation by the ABPI is the code of practice known througout the industry as 'The Code'. The Code outlines the rules for promoting prescription medicines, and therefore serves as the regulationy backbone for all of the activities explored in this thesis. The Code is revised every year or so, with the most recent version being released in 2016. For the purposes of this research, I have obtained all eight codes of practice (plus one addendum) from 2006 to 2016, as well as two which predates that period. Each year the number of pages increase (except in 2014-2015 where the number of pages stayed at 71), reflecting an overall trend in increasing regulation. More recent iterations of the code have seen the inclusion of sections on issues such as how to interact with patient groups, as well as the content of pharma-funded medical education. Conversely, rules on the value of gifts PSRs are asllowed to give to healthcare professionals have been scrapped in favour of an allout-ban. It is likely that this ban corresponds with the 2010 Anti-Bribary Act, a law which covers all businesses but is frequently cited as impacting most heaviliy on the pharmaceutical industry. The prescise impact of these changes in regulation will be explored in the following chapters.

Infractions of The Code are dealt with by the PMCPA. Set up by the ABPI in 1993, the PMCPA holds courtlike hearings on alleged infractions to the ABPI code of practice. These take place in response to reports from other pharmacuetical companies, the media or the public that rules have been broken. Similarly to a court, the PMCPA explores whether an infraction has taken place, and what the reprocussions should be. The PMCPA highlights on their webside that they are 'the self-regulatory body which administers the Association of the British Pharmaceutical Industry's (ABPI) Code of Practice for the Pharmaceutical Industry independently of the ABPI' (PCMPA

2018). Within their own definition, they characterise themselves as both outsiders ('independent') and insiders ('self-regulatory'). They promote the idea of being separate from the ABPI, whilst, simultaneously, occupying the same floor of the same building on Victoria Street, London (ABPI 2018; PCMPA 2018).

The PMCPA was established after Herxheimer and Colliers' (1990) article criticising the ABPIs enforcement of The Code and monitoring of infractions. Ironically, Herxheimer and Collier (1990) noted that self-regulation favours regulating that which can be publically criticised. Twenty-eight years ago, Herxheimer and Collier (1990) succinctly explained 'The ABPI's wish to secure compliance with the code seems weaker than its wish to pre-empt outside criticism and action: its self-regulation seems to be a service to itself rather than to the public' (1990, p. 307). As discussed previously, the industry has been at the centre of numerous scandals since this article was published. However, the pharmaceutical industry continues to be self-regulated.

The findings that are presented in the following chapters of this thesis emphasise the persisting relevence of Herxheimer and Colliers' (1990) assessment. Abraham (2008) purports that we can assume overall 'objective interests' which go beyond individual behaviours or actions. With respect to the pharmaceutical companies, their objective interest is to maximise profits. This idea is in keeping with Bakan's (2010) characterisation of corporations as psychopaths, who must always act in their self-interest. Therefore, although the following pages paint the picture of an increasingly regulated industry, self-regulation, by definition, must always be selfish regulation.

6.5 Marketing Methods

As said previously, marketing has arguably become the core activity of large pharmceutical companies. The self-regulation of the pharmaceutical industry is perhaps most apparent when looking at companies' marketing practices, as these are solely regulated by the ABPI. Marketing activities are therefore entirely self-regulated. Exploring marketing activities therefore provides a great deal of insight into the motives of the industry's key players. Marketing regulations are published and frequently updated in the ABPI Code of Practice ('The Code') which is available online. Further to this, Malerba and Orsenigo (2015) found that marketing is now the core competency

of large pharmaceutical companies. Due to the outsourcing of research and development, such companies have become primarily marketing organisations. For these reasons, this thesis focuses on how pharmaceutical companies market their products. Prozac is frequently cited as one of the most iconic pharmaceutical brands of all time due to its successful marketing campaign, which makes antidepressants an ideal drug class to examine.

Modern pharmaceutical companies use a variety of methods and approaches to promote their products. What follows is an overview of the core techniques used by companies to promote prescription medications, and an explanation of how they feature in this thesis. However, as the industry morphs and adapts in response to new guidelines and societal changes, the methods adopted by companies shift and blur accordingly. Consequently, this should not be understood as an exhaustive list, but, rather, an overview of the different 'flavours' of marketing methods used.

Prescription medications cannot be advertised directly to the public; therefore, healthcare professionals are the primary targets of marketing messages. PSRs, commonly known as drug reps, are industry employees who have direct contact with healthcare professionals. They visit healthcare providers to inform them about (and promote) their company's new medications. In response to regulatory changes and various scandals, the role of PSRs has changed in recent years, which will be explored in detail in the following chapter.

PSRs are often also responsible for recruiting KOLs. KOLs are high status individuals who are respected in their field. Ordinarily, they are consultants and/or senior academics who are the tastemakers within healthcare practice. They may work for the industry by advising them on their marketing strategy and research methods, or by speaking publicly at industry funded engagements. Such engagements are often events where healthcare professionals receive continuing professional development (CPD) to keep their medical knowledge up-to-date. Companies also fund healthcare professional's attendance at conferences where they invariably have a presence, using stands and posters to promote their newest medications. The interaction

between healthcare professionals and the pharmaceutical industry will be discussed in Chapter 8.

Although, as aforesaid, pharmaceutical companies cannot advertise directly to consumers, they can fund campaigns aimed at raising public awareness about a condition. Such campaigns are often mediated by PR companies who work more broadly to massage the public image of pharmaceutical companies. These activities are explored in Chapter 9.

The most overt and observable instance of such marketing can be found in trade publications and academic journals. Adverts usually take the form of either one-page or two-page spreads, which include images and information about the drug. Below is an example of a journal advert for antidepressant Valdoxan, which demonstrates the kind of imagery and messages which can be found in such adverts.

Figure 2: Valdoxan Advert



Whilst gathering data for this thesis, I collected dozens of printed journal adverts. However, this marketing method is currently in a state of flux, as most healthcare professionals now view journals online with banner adverts that I have been unable to obtain copies of. No healthcare professionals I spoke to reported reading print journals. Therefore, rather than dedicate a whole chapter to the analysis of such documents, I chose to draw upon them instead as evidence of companies' core marketing messages in other chapters. For example, in Chapter 9 I demonstrate how disease awareness campaigns funded by pharmaceutical companies can be used to covertly regurgitate marketing messages.

6.6 Conclusion

Although hard to imagine in a post 'Bad Pharma' (Goldacre 2012) world, the pharmaceutical industry was once highly trusted. Developers of life-saving innovations, many drugs developed during this time had a positive impact on both life expectancy and quality of life. However, as time progressed the cost of being innovative increased. In response to this pressure, large companies have outsourced research and development to instead focus on marketing, which is entirely self-regulated.

The reputation of the industry has plummeted since the 1990s in response to numerous scandals. Scandals involving antidepressants have served as a lightning rod for reducing public and professional trust in the industry. The issues highlighted in this chapter, including loss of reputation, self-interested regulation, and an increased focus on marketing are key for understanding the landscape of the modern antidepressant market. Each of the following findings chapters explores a smaller, more contained section of the larger biome. However, the issues outlined in this chapter are pervasive throughout. The following chapter develops in greater detail Conrad's (2005) point about the increasing dominance of the pharmaceutical industry as a driver of medicalisation, through focusing on those directly involved in the promotion of antidepressants: PSRs.

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7. Pharmaceutical Sales Representatives

7.1 Introduction

The previous chapter established that marketing has become the central activity of modern pharmaceutical companies. Leask (2002) wrote about the 'muscle marketing' that took place in the mid-20th century. This aggressive marketing was delivered by a travelling salesforce referred to at the time as 'detailmen'. Detailmen visited healthcare professionals and provided them with 'details' about new drugs (thus the name detailmen). Although the term detailman has long since died out, pharmaceutical marketing is still dominated by a travelling salesforce, now commonly referred to as PSRs or 'drug reps.' As I write this, the recruitment agency 'Indeed; is currently hosting 437 job adverts for PSRs in the UK (in comparison, they are advertising 288 business management lecturer positions, 38 social science post-docs and 3739 barista jobs...) Evidently, these staff remain central to the marketing strategy of antidepressant manufacturers. They are the front-line, the industry foot soldiers (Fisher 1991). Their first-hand experience of promoting antidepressants to healthcare professionals make them integral to this investigation.

Conrad (2005) argues that medicalisation is now driven primarily by pharmaceutical companies, but more details are required about how this works in practice. PSRs are on the front-line of the industry, communicating with customers on a daily basis, and promoting the messages of the company. Therefore, they provide a unique insight into the industry's role in medicalisation. This chapter focuses on the information obtained from the interviews conducted with eight PSRs. Specifically, it explores their accounts in terms of what they tell us about the broader issues in antidepressant marketing. The chapter begins by defining the role of PSRs, highlighting how the terminology around sales work has changed in recent years. Following on from this discussion, PSRs' accounts of their sales strategies are presented. Finally, attention will be turned to regulation and how changes in regulation have impacted upon the activities of PSRs, and, in turn, what this means for antidepressant marketing.

Each informant was selected on the basis of their experience working for companies that market antidepressants. However, they each also had a background in promoting
a variety of drugs for physical and mental-health conditions, and observed that their experiences across these respective classes of drugs were very similar. Because of this, informants often spoke in broad terms about their activities, rather than referring to any single drug. The few instances where informants highlighted a specific difference in relation to antidepressants will be discussed in detail.

7.2 Who are they and what do they do?

As discussed in the methods chapter, this thesis is influenced by the work of Derek Layder (1993); in particular, his argument for foregrounding history and context in research. This section therefore sets out by examining the professional backgrounds of the PSRs interviewed. Secondly, I focus on the various job titles held by the informants, questioning whether the morally 'dirty' nature of the job has contributed to a rebranding of these roles.

7.2.1 Professional backgrounds

In 2005, The New York Times published an article by Stephanie Saul on the industry hiring practices for PSRs. The article, titled 'Give me and Rx: Cheerleaders Pep-up Drug Sales' accused the industry of seeking out and hiring cheerleaders from university cheer-squads (Saul 2005). One cheerleading coach interviewed for the piece noted that '[the pharmaceutical company] don't ask what the major is...Exaggerated motions, exaggerated smiles, exaggerated enthusiasm – [the cheerleaders] learn those things, and they can get people to do what they want.' (Saul 2005, p. 28). Whilst no academic research has been conducted into this specific phenomenon, authors with medical backgrounds who have had contact with PSRs often characterise them as overwhelmingly attractive and friendly.

Whilst cheerleading is not as popular in the UK, UK-based PRSs have still been described by authors as young, charming, attentive and attractive (e.g. Goldacre 2012, p. 279). Although very friendly, none of the PSR informants I spoke to divulged a history in cheerleading. However, they did discuss how they got started in the industry. Four entered the job directly from university with no prior experience in medicine (Reps 1 2,3 and 4). Three entered the industry having already established a medical career in nursing or pharmacy (Reps 5,6, and 7). These PSRs were recruited by PSRs whilst

working in their medical role. The remaining PSR had established a career in a nonmedical field prior to transitioning into the industry (Rep 8).

The professional background of the informants was particularly relevant in the case of those who had a history in medicine. These informants spoke passionately about patient outcomes and how their training on 'the other side of the counter' enabled them to better serve patients. Furthermore, they were less likely to use words such as 'sales' and 'customer' than those PSRs whose careers began in industry. Prior to interviewing these informants, I had been unaware of pharmaceutical companies hiring PSRs with medical backgrounds. This strategy conflicts with the typical stereotype of PSRs as young, sales-minded individuals. Instead, these informants were more mature, having already established a career prior to joining the industry, and were thus acutely aware of the impact their actions had on patients and the wider medical establishment. The unexpected diversity in the professional backgrounds of PSR informants is in keeping with a wider strategic shift observed in this thesis, which will be explored in detail in the second half of this chapter.

7.2.2 Job Titles

The term 'drug rep' can be found in almost every book criticising pharmaceutical industry practices (Goldacre 2012), as well as in film and television (e.g. Zwick 2010). The term is shorthand for PSR, which has traditionally referred to pharmaceutical industry employees who visit healthcare professionals to provide promotional information on drugs. However, the role of PSRs has broadened. In the ABPI code of practice, such employees are referred to simply as 'representatives.' It notes: 'The term "representative" means a representative calling on members of the health professions and other relevant decision-makers in relation to the promotion of medicines.' (ABPI 2016, p. 6). In addition to selling and promoting to prescribers, representatives are also involved in influencing decision-makers to get drugs approved, get them on formularies and change policies. The evolving responsibilities of PSRs has contributed to the splintering of the role into numerous similar, but slightly different, roles (see Figure 3), such as key account manager, territory business manager, NHS liaison manager, NHS project co-ordinator, medical representative and hospital specialist, amongst others. Informants explained that role requirements and

terminology differ between companies, but that there is invariably a hierarchy with more sales-oriented jobs towards the bottom, and policy-oriented jobs towards the top.

There is a bit of a hierarchy so you kind of work your way up in the industry. So, you start with GPs, then there's hospital specialist, then there is some kind of NHS liaison which is now kind of a market access type role, where you go and speak to budget holders and affect policy and guidelines and visit healthcare professionals, so that's kind of the next level up (Fieldwork Interview, PSR 8).





None of my informants currently held the traditional title of PSR. Instead, most held roles such as key-account manager, hospital specialist, etc. Whilst PSR still has some usage, it is decreasing in popularity in favour of alternative job titles. As mentioned previously, this is likely due, in part, to the changing marketplace, and changing responsibilities of representatives; however, there may also be other contributing factors to these changes.

For instance, the roles of representatives are becoming more difficult to decode, whilst the responsibilities of the individual are not always clearly identified by their title. When asked what their job entailed, one informant, whose specific job title I will not name for anonymity purposes, responded, 'It's a fancy title for a sales role' (PSR 2). Although all my respondents engaged in self-described 'selling' activities, none of them had the term 'sales' explicitly in their job titles. Furthermore, the term 'pharmaceutical' was absent from all job titles.

One theory for this change can be attributed to the idea of 'dirty work'. The term dirty work was coined to refer to those occupations which may be perceived as degrading or disgusting (Hughes 1962). Whilst promoting pharmaceuticals is not dirty work in the same way as collecting rubbish or working with sewage, it could be considered morally dirty work. As Paharia et al. (2009) characterise, it is dirty work with 'clean hands'. Morally dirty work is work which is stigmatised by society because of the ethical implications of the work. Examples of such occupations might be telemarketers, debt collectors and tabloid reporters (Ashforth and Kreiner 1999). Paharia et al. (2009) single out the pharmaceutical industry as morally dirty work in contemporary societies.

In their review of existing literature on dirty work, Ashforth and Kreiner (1999) found that dirty workers were acutely aware of the social stigma associated with their profession. Contrary to expectations, however, the 'dirtier' the work, the higher the occupational esteem associated with it. Therefore, those doing morally objectionable jobs often fail to experience shame or doubt about their professions. Indeed, the informants I spoke to reproduced this narrative. Whilst they acknowledged the poor reputation of the industry and lamented its portrayal in the media, they nevertheless expressed pride in the work they did. The informant quoted below presented a view of the media which was common amongst all PSR informants. They highlight how their job (selling) can have positive consequences.

I think generally good news doesn't make the headlines does it. It's normally this drug costs this much money and the company refused to drop the prices, or this NHS trust can't afford funding in this postcode for this drug and it's very rare that ... I mean you kind of see positive things when you hear there's been a new breakthrough in this or a new breakthrough in that, but I think it very rarely puts it down to the fact that it's been all the money from selling past drugs that's meant that's happened, so I still think there's a lot more that could be done to improve from a media perspective the industry... the take on how people view the industry (Fieldwork Interview, PSR 1). Ashforth and Kreiner (1999) sought to investigate this dichotomy of those who work in a stigmatised profession without feeling any shame. The extract above exemplifies what they refer to as reframing (Ashforth and Kreiner 1999, p. 421). This is when workers devalue negative attributions and recast their work in a positive light. This, once again, was common amongst the informants, who invariably focused on how their role in creating profit for their company had a positive societal impact (as with PSR 1), or helped patients.

The authors also found that a similar phenomenon of 'refocussing' helped increase esteem among dirty workers. That is, ignoring the aspects of the job which are socially stigmatided and focusing instead on those which are less so. The evolution and diversification of job titles for PSRs may be an example of companies encouraging this refocussing, and attempting to increase occupational esteem. Removing the words 'pharmaceutical' and 'sales' and replacing them with words like 'medical', 'specialist' and 'manager' may encourage workers to focus on the less stigmatised aspects of their jobs. Job titles can therefore be used to mitigate the stigma associated with dirty work, as they can be rebranded to construct a positive identity (Ashforth and Kreiner 1999).

Therefore, it appears that the stigma associated with sales, the pharmaceutical industry, and the intersection of these in the term 'PSR' has also contributed towards this change in terminology, particularly in the wake of the Seroxat scandal and others. Although none of the employees I interviewed currently held the job title of PSR, the term is still used as an umbrella term by informants and regulators. In this thesis, I therefore continue to refer to all those informants who engage with healthcare professionals with the aim of promoting a medication as PSRs. As exemplified by Rep 2, a sales role with a fancy title is still a sales role... or is it?

7.3 Are Drug Reps the Devil's Foot-Soldiers?

Earlier in this chapter, I presented the argument that the job titles of PSRs had changed in response to increased stigma. This section explores if and how the jobs themselves have changed. I discuss whether PSRs remain primarily sales people, or if, in response to scandals and increased regulation, they have become technocratic experts. I begin by considering the critical argument that PSRs are simply sales-people using manipulative strategies to promote the prescription of their product. Secondly, I question the idea that PSRs have evolved along with their job titles, becoming objective experts who operate without an agenda. Ultimately, I draw upon Abraham's (2008) notion of 'neo-liberal corporate bias' to argue that the improvements in the practices of PSRs, whilst rendering old stereotypes obsolete, are driven by enlightened self-interest, rather than out of a duty to patients.

7.3.1 PSRs as Manipulators

In the Hollywood film *Love and Other Drugs*, Jake Gyllenhaal plays, Jamie, who is a PSR. Jamie is trying to persuade doctors to switch from Prozac to Zoloft, using his charm and charisma to manipulate staff at surgeries. Adhering to the stereotypes outlined in the previous section, he is young and attractive, seducing everyone in his wake. In an interview on the podcast *Science Vs.*, Dr David Tauben discussed how seduction can lead to increased prescriptions.

It's seductive. And I use the word intentionally because it's seductive to be able to do something so difficult so simply [treat a condition with a pill]... ...It's seductive when you get pens and coffee mugs that market the product, and it's seductive when they pick super attractive people (PSRs) (cited in Zuckerman 2018).

Although 'sales' is no longer a word commonly used in the job titles of PSRs, PSR 2 suggested that, at their core, all such roles are sales roles. Indeed, one healthcare professional I spoke to who trained PSRs likened the role to selling cornflakes. Numerous studies have found that engaging with PSRs has an impact on healthcare professionals' prescribing patterns (Muikers et al. 2005; Katz et al. 2010). Healthcare professionals who interact with PSRs are also significantly more likely to prescribe new medications. This is why ex-rep Fugh-Berman and co-author Ahari (2007) suggest that PSRs have too much impact on prescribing decisions. This undue influence is reported as stemming from the use of questionable practices to manipulate prescribers. For example, the use of personality typing to target prescribers has been described in detail in extant literature and supports the stereotypical image of PSRs as manipulative. Furthermore, the practice of PSRs providing healthcare professionals

with gifts and hospitality has been criticised for its impact on prescribing (Katz et al. 2010). This section presents an analysis of the use of these techniques and examines how they relate towards the negative perception of PSRs.

7.311 Personality Typing

Several ex-PSRs have written books and academic journal articles detailing the strategies they were taught to use whilst working in the industry (Oldani 2004; Reidy 2005; Fugh-Berman and Ahari 2007). One common strategy discussed in all these accounts is personality typing. Fugh-Berman and Ahari (2007:621) noted that PSRs are trained to 'assess physicians' personalities, practice styles and preferences.' The use of personality typing is pointed to by whistle-blowers as evidence of PSRs' ability to covertly manipulate prescribers, and, as such, undermine evidence-based medicine.

Personality typing is predicated on the idea that understanding the inner workings of a person gives rise to insight about how best to sell to them. In marketing terms, it can be referred to as a 'micro-segmentation' technique, which itself falls under the slightly broader umbrella of psychographics. According to McDonald and Dunbar (2004), psychographics refers to 'a customer's inner feelings and predisposition to behave in certain ways' (p 158). There are various psychographic segmentation models which are popular in business-to-business selling, as evidenced in Figure 4 below which is taken from Barry and Weinstein (2009).

| Typology Underpinnings | Psychographic Classifications | | | | | | |
|---|--|--|---|---|--|--|--|
| Maslow's Hierarchy of Needs Theory | Survivors | Security Conscious | Belongers | Egos | Self-Actualists | | |
| | Seeks cost savings | Seek information & assurance | Seek affiliation & free time | Seek recognition & promotion | Seek achievement & job fulfilment | | |
| Cameron & Freeman Model of Organisational Culture Types | Clans | Hierarchies | Markets | Adhocracies | | | |
| | Seek teamwork & loyalty | Seek policies adherence & smooth operations | Seek competitive advantage | Seek innovation, growth & flexibility | | | |
| CEO Objectives | Loving Parents | Autocrats | Empire Builders | Fortune Hunters | | | |
| | Seeks long- term financial stability | Seeks course direction | Seeks business growth | Seeks results in real asset growth | | | |
| Myers & Snow (1978) Typology | Prospector | Defender | Reactor | Analyser | | | |
| | Seeks innovation | Seeks efficiency | Seeks evidence of success | Seek later adoption of differentiation | | | |
| Phase of the Purchase Decision Purchase | First Time Prospects | Novices | | Sophisticates | | | |
| | Seek trust, information & hand holding | Seek help to make product work for them | | Seek technology talk, compatibility & customisation | | | |
| Product Life Cycle Theory | Programmed Buyers | Relationship Buyers | Transaction Buyers | Bargain Hunters | | | |
| | Seek supplier rotation | Seek partnerships | Seek best price & service trade-off | Seek large price discount | | | |

Figure 4: Psychographic classifications (Barry and Weinstein 2009)

| | Innovators | Optimisers | Operationalisers | Economisers | |
|---|---|---|--|--|--|
| Generic Customer Value Segment Matrix | Seek leading ideas or technology to create edge | Seek fast & responsive support to make transitions | Seek supply chain optimisation support | Seek continuous cost reduction | |
| Miller Heiman Executive Impact & Large Account Mgmt Process (LAMP) | Charismatics | Thinkers | Skeptics | Followers | Controllers |
| | Seek new, bold & innovative ideas | Seek decision making methodology (review every pro/con) | Seek only those things that fit their world view | Seek similarity of decisions to those made in the past | Seek to manage every aspect of the decision |
| Beren's Interaction Styles Model, Social Styles models and DiSC® | Chart-the- Course | Behind-the- Scenes | In-Charge | Get-Things-Going | |
| | Seek to get desired result | Seek to get an integrated result | Seek to get an achievable result | Seek to get an embraced result | |
| Forrester Research Technographics | Cyber Snobs | Fast Forwards | Hand Shakers | Mouse Potatoes | Traditionalists |
| | Seeks frequent upgrades & trendy technologies | Seek time savings & productivity- oriented technologies | Seek affiliation & free time | Seek recognition & promotion | Seek achievement & job fulfillment |
| NA | Progressives | Black Box Devotees | Show Me's | Non- Believers | No Perceived Needs |
| | Seek technology innovation | Seek simplicity | Seek demonstration of success | Seek evidence | Seek reason to purchase |
| BioInformatics Scientific Personality Assessment | Enthusiast | Explorer | Leader | Organiser | |
| | Seek to interact & reach group consensus | Seek to venture into uncharted territories | Seek to guide & manage other researchers | Seek cautious decision making from facts & data | |

As discussed in the previous section, PSRs engage with healthcare professionals who are primarily involved in prescribing or setting budgets and guidelines. Not all of the models outlined by Barry and Weinstein (2009) are relevant for my purposes here in this research. Indeed, there are other relevant models not outlined in this table, but it still offers insight into the nature of such typologies. Typically, sales people are directed to assess the psychographic attributes of an individual (e.g. personality, beliefs, values), assign them to a class based on their findings, and then tailor their sales pitch to reflect the classification of the individual.

Fugh-Berman and Ahari's (2007) paper is now over a decade old and is focused exclusively on Ahari's own experiences as a PSR in the US. However, my informants reported that personality typing is also used in the UK. They referred to some of the classifications included in the Myers and Snow typology and LAMP listed in Figure 4 above, as well as the notorious Myers-Briggs personality test and other typologies.

It's just understanding how different people work. So, there's loads of different models, but you know, different colours, or you know like the Myers-Briggs type indicator... kind of typing people and adapting your style for those people so that you get on with them, basically as customers, or have the best possible chance of having a relationship with them (Fieldwork Interview, PSR 1).

The informant framed the approach as relationship-building and facilitating good lines of communication. After disclosing this approach, the informant added:

That's not meant to sound manipulative in any way, it's just, you know, management skills I guess (Fieldwork Interview, PSR 1)

All informants were acutely aware of the 'unethical' reputation of the pharmaceutical industry, and the criticisms regarding their influence as PSRs. The informant was keen to clarify that the approach was not intended to be manipulative. However, the line between what constitutes good communication and what is, in fact, manipulation is blurry, as evidenced by the ongoing debate surrounding targeted online advertising (Persily 2017). Having utilised psychographic methods throughout their career, one informant spoke of the personality trends they had identified within different specialties:

Each specialty has its own personal traits. Orthopaedic surgeons tend to be alpha male, headstrong, kind of God-like figures who are quite brash and racist and sexist and the rest of it ... whereas rheumatologists are soft, dermatologists very wet. You know, GPs tend to be quite boring. It's easy to put them into a category, although it's probably slightly unfair. But, yeah, psychiatrists tend to be slightly more eccentric, less rigid in terms of what their thoughts are in terms of prescribing. Keener to try new medication' (Fieldwork Interview, PSR 3).

This informant enjoyed working on psychiatric medications due to the perceived openness of psychiatrists. A PSR selling an antidepressant can interact with psychiatrists, GPs, or a combination of the two. It is possible that the differences between GPs and Psychiatrists observed by this informant were, in part, related to their relationship to the medicine they were promoting. GPs treat mild to moderate depression and, indeed, GP informants reported sticking quite rigidly to formal guidelines from NICE or their commissioning group. Conversely, psychiatrists see patients with severe, or 'treatment resistant', depression where the patient has not responded to previous medications. They thus have more freedom in prescribing branded antidepressants. This informant also noted that, as long as the healthcare professional was somewhat open to prescribing new medication, they could have 'a lot' of influence on prescribing. This acknowledgement was an anomaly in the interviews. Most PSR informants framed their work as primarily communicating information. They noted that, due to the distance between their conversation with the healthcare professional and the healthcare professional's decision to prescribe, they had little control over the situation. This contradicts existing research which suggests PSRs have considerable influence on prescribing (e.g. Muikers et al. 2005; Katz et al. 2010). Such research tends to compare the prescribing patterns of those who do see PSRs against those who do not, rather than comparing the effectiveness of different PSRs.

Hospitality

PSRs organise meetings with healthcare professionals to discuss their product and/or the broader disease area. Historically, this has included flying healthcare professionals to exotic locations and feeding them expensive meals. Examples such as these are verified by healthcare professional informants who were afforded such experiences by PSRs promoting antidepressants during the Prozac boom of the 1990s. Their role as recipients of such hospitality is discussed in more detail in the following chapter. This section focuses on the use of hospitality by PSRs to facilitate sales.

Although examples of lavish hospitality are prevalent in accounts of activities in the 1990s and in wider popular culture, more recently The Code has incorporated stricter rules regarding hospitality. The 2016 ABPI code of practice has over two-pages dedicated to the regulation of meetings, hospitality and sponsorship. The following two extracts articulate the core tenets of the regulation.

the venue must be appropriate and conducive to the main purpose of the meeting; lavish, extravagant or deluxe venues must not be used, companies must not sponsor or organise entertainment (such as sporting or leisure events) and companies should avoid using venues that are renowned for their entertainment facilities

and

the subsistence associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion (ABPI 2016, p. 32)

Prior to these changes in regulation, PSRs were able to take healthcare professionals for expensive meals at lavish locations. The most scandalous example in the literature on PSR hospitality describes PSRs taking healthcare professionals to a strip club (Goldacre 2012, p. 281). The PSRs I spoke to only admitted to taking healthcare professionals for meals:

I would have been allowed to have presented my product and um, talked to the doctors about a product, and then they would have sat somewhere else separate to the general public and had a meal (Fieldwork Interview, PSR 8)

If the meal did not take place anywhere overly lavish, and cost less than £75 per-head (which, arguably, is still fairly lavish) then it is possible that such a meal would still be permissible today. One PSR noted that healthcare professionals became so accustomed to having the industry pay for hospitality, that they felt they deserved payment simply for listening to the PSR.

People were asking you to sponsor a lunch meeting at a GP practice and you'd turn up and an invoice is provided, and you are expected to pay. There was no food and there was no other content of any financial sort of thing that had cost money, and yet there was an insistence that that opportunity to come and talk about your product you would pay. Although it was never termed in that way and I came across that in a few instances ... I felt that it was an abuse by the healthcare professional of what they saw as an opportunity potentially just to charge sales reps for coming and speaking to them (Fieldwork Interview, PSR 2)

This example would certainly represent a breach of The Code today, however due to the historical nature of the example it is unlikely that it constituted a breach at the time. None of the PSR informants I spoke to reported breaching any regulation regarding the provision of hospitality for healthcare professionals. However, breaches have occurred. When breaches are reported and investigated, they are published on the website of the PMCPA, the organisation set up by the ABPI to assess complaints. One such example was investigated by the PCMPA after an ex-employee of Cephalon leaked a document which had been circulated to employees.

The document included feedback from delegates the company had sponsored to attend a European congress in Lisbon. Testimony from the PSR included in the document stated 'we then went to a few bars and to a club until 3am – a few good photos to prove it!!!'(PCMPA 2010). Receipts provided for the investigation highlighted that early-morning cocktails and spirits had been purchased for delegates using company money, in addition to evening meals ranging from £43-57 per-head, whilst on one evening the delegates had been taken to see a group of fire eaters. The PCMPA panel assessing the case concluded that the hospitality was not secondary to the congress, but, rather, the trip appeared to be a social event with a 'general party mood'. A core concern of the panel, which is a branch of the industry's self-regulation, was the impact that such activities would have on the reputation of the industry. The panel ultimately concluded that the company were guilty of providing excessive hospitality and 'bringing discredit upon and reducing confidence in the pharmaceutical industry'.

There are other examples of hospitality related breaches on the PCMPA website, however they appear to be relatively rare. In 2016, two cases related to hospitality and travel for healthcare professionals were found to be in breach of the ABPI code of practice. One found Actelion guilty of distributing frozen yoghurt at an exhibition stand (only limited quantities of biscuits, sweets or fruit are acceptable). The other, after a complaint raised by The Daily Telegraph, found Hospira guilty of flying UK healthcare professionals abroad without a valid and cogent reason. Once again, this was deemed by the PCMPA as bringing discredit to the industry. Although these instances are rare, they testify to the principal motive of the ABPI in regulating hospitality: protecting the reputation of the industry.

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In the early 2000s, the activist group 'No Free Lunch' (No Free Lunch 2017) ran a 'pen amnesty' whereby they encouraged healthcare professionals to send them their pharmaceutical industry branded pens. For every pen sent by a healthcare professional, they would receive a No Free Lunch pen in return. The 'pen amnesty' has since ceased as, due to the sheer number of branded pens they were receiving, they could not afford enough pens to replace them. The pharmaceutical industry branded pen has since become iconic, and serves as a lightning rod for the wider issue of small gift-giving by pharmaceutical companies to healthcare professionals.

Despite ongoing criticism, the 2006 version of the ABPI code of practice still allowed PSRs to distribute 'low-value' gifts to healthcare professionals and other decision-makers:

A low-value promotional aid is one that has cost the donor company no more than £6, excluding VAT. The perceived value to the recipient must be similar. Items deemed unacceptable include those for use at home, such as table mats and road atlases. Acceptable items include pens and diaries. Provided that a promotional aid bears no more about the product than the brand or non-proprietary name and the company name, there is no need to include prescribing information (ABPI 2006, p. 28)

PSR informants recalled how gift-giving was commonplace throughout this time:

I would remember as a GP representative I'd have pens and I'd have post-it notes, and I'd have clocks and I'd have gloves, and sanitiser and they would all be branded with the company's products on. And I'd have my garage with boxes of the stuff and I'd hand it all out in surgeries, and, obviously, that would leave little brand reminders with the different products around in the surgeries (Fieldwork Interview, PSR 8).

The industry did the whole branded items, here's a load of pens, here's a load of post-its, here's some sandwiches, here listen to me and I'll give you a nice lunch while I blabber on about my product, and I think a lot of customers in the NHS have experienced that for a number of years (Fieldwork Interview, PSR 7).

Within the medical profession, branded pens became something of a joke. However, Katz et al. (2010) found that even low-value gifts, permitted by The Code, can influence prescribing patterns. Katz et al. (2010) demonstrated that when a gift is received, even one of little value, a precedent is nonetheless set whereby the receiver feels somewhat

Gifts

obliged to return the favour. Social psychologists theorise that this feeling of obligation is subconsciously influenced by 'reciprocity norms' (Sah and Fugh-Berman 2013). Moreover, the continuing physical presence of the brand within the prescriber's office can itself be a form of influence. Indeed, prescribers may unconsciously develop trust in a brand simply from seeing it every day in their pen pot. As one informant noted, the decision to prescribe one medication over another is not always based on evidence alone:

Part of it's going to be based on data, but every decision in life is based on an emotional factor as well and, simply put, if you added up all the attributes and data of one product, one pharmaceutical product and compared them in a great big table next to another product, I, or even a highly trained doctor, wouldn't be able to compute precisely the variables between those two things. You've got to come into an element of emotion around the choice they're making. Whether that's familiarity, or whether that's whatever else that may be (Fieldwork Interview, PSR 2).

The idea that gift-giving increases familiarity with a brand was a key motivation cited by informants, who referred to such gifts as 'brand reminders' (PSR 8). The most recent version of The Code adopts a much stricter stance on small gift-giving:

Gifts such as coffee mugs, stationery, computer accessories, diaries, calendars and the like are not acceptable. Gifts of items for use with patients in the clinic, surgery or treatment room etc, such as surgical gloves, nail brushes, tongue depressors, tissues and the like, are also not acceptable. Items such as toys and puzzles intended for children to play with while waiting must not be provided. Gifts of items for use in the home or car are unacceptable. (ABPI 2016, p. 27)

In this version of The Code the only gifts PSRs can leave are educational materials, such as leaflets, books, and cheap DVDs, which cannot be overwritten with other data. These changes to The Code demonstrate that the pharmaceutical industry is becoming more regulated in response to ongoing criticism. The oft-referred to stereotypes of PSRs using gifts and lavish hospitality to manipulate doctors into prescribing their employer's drug are therefore out-of-date in the UK context.

7.3.2 PSRs as Technocratic Experts

Thus far, the critical portrayal of PSRs as covert marketeers and manipulators has been explored and critiqued. Evidence suggests that PSRs did historically wield too much influence. Rather than being guided by medical facts, prescribers were, albeit only to some extent, influenced by the gifts and hospitality administered by PSRs. More recently, changes in regulation have reduced the capacity of PSRs to influence prescribers in this way. So, in the absence of branded pens and fancy hotels, what do PSRs do now? This section explores the notion that the role of a PSR has become more technocratic, that is, that they have evolved from acting as purely sales-people to patient-focused experts. Firstly, two core PSR strategies are presented which are suggestive of this move away from prioritising profits at all costs towards prioritising patient outcomes. The PSRs interviewed felt strongly that the industry has changed for the better, and, as such, that the critical view of the industry presented in books such as 'Bad Pharma' are out-of-date. With this in mind, the section concludes by outlining their views on the ethics of the industry.

'The Right Patient'

One strategy mentioned by almost every PSR informant centred on being 'patientfocused' and specifying 'the right patient' for the drug. One informant, an ex-nurse, spoke passionately about using their role to improve the lives of patients.

I talked very much about the right kind of patients and how it would benefit a patient ... and, you know, not downplaying any side-effects and things but helping to educate doctors or the nurses about how they might manage that particular side-effect to make sure the experience for the patient was as good as possible as well (Fieldwork Interview, PSR 5)

Whilst this informant was particularly empathetic towards patient needs, perhaps as a result of their history in nursing, other informants specified that being 'patient-focused' was not purely altruistic, as highlighting the 'right patient' also had commercial benefits.

If you actually do your job and you put the patient, whoever the patient is in your particular disease area, if you put the patient at the centre of the work you're doing, whether that's project work, whether it's conversations with clinicians, you always focus on the patient, then actually, you won't go far wrong because that's what people (healthcare professionals) are trying to do ... What you're trying to do as a company is get much more effective care in the particular disease area you're working in (Fieldwork Interview, PSR 8)

In this way, being patient-focused works in an analogous fashion to profiling the personality types of healthcare professionals. Healthcare professionals are motivated by wanting to help their patients, therefore PSRs can use being patient-focused as a means through which to build trust and rapport. Furthermore, PSRs reported using patients as illustrations, asking the healthcare professional, for example, to imagine the next patient they encountered who had treatment resistant depression or suffered from certain negative-side effects. The PSR would then talk about how trying their medication with that patient could be beneficial. The term 'appropriate use' also occurred several times to describe a medicine being prescribed only with the 'the right patient' and in the correct dosage.

'A large part of training is to get (PSRs) to be patient-focused and to make sure they identify, or help medical people identify the right person who will benefit the most from any particular treatment they're involved in selling ... It's always about appropriate use and who those patients should be. I think, overall, it's very patient-focused, but with a commercial aspect which, unfortunately, wins the day. But, as I say, we wouldn't be here if we didn't do that. If you let your heart rule your head every time you'd be bankrupt, believe me' (Fieldwork Interview, PSR 6)

The need to specify that they are promoting the drug only for usage in patients who will benefit from taking it should be redundant. However, the 'Seroxat Scandal' serves as a powerful example of how antidepressants have historically been promoted for inappropriate usage in adolescents, which, ultimately, resulted in suicides. In the wake of such scandals, the industry is keen to improve its reputation and avoid future scandals. Therefore, this promotion of 'appropriate use' in 'the right patient' should lead to healthcare professionals having a positive experience when prescribing the drug and, in turn, making them more likely to prescribe it again, rather than experiencing a bad reaction which could lead to another scandal or the healthcare professional never prescribing the drug again.

Overall, the interview data suggests that the profit motive still drives the strategy enacted by PSRs. This is reflected in the personality typing which is still in use, however it also influences more 'ethical' approaches such as being patient-focused.

Key Account Management

The use of the title 'key account manager' by many companies to describe their PSRs is reflective of a broader shift in sales strategy. The term key account management (KAM) derives from business-to-business marketing, whilst academics have attempted to pin down its precise definition for decades. Drawing upon previous efforts to define the term, informed by their own consultancy work within the pharmaceutical industry, Smith (2009) identified five ways in which KAM differs from traditional sales management. The first way in which KAM differs from traditional sales management is that 'Key accounts create more than financial value' (Smith 2009, p 90). This means that, in addition to financial value, KAMs are providing other 'values' in the form of relationships and possibly services. The other differences Smith identifies centre around the 'value' posed to both sides: 'Key accounts are key to both partners' (2009, p 90), 'Key accounts have longevity' (2009, p 91), 'Key account managers facilitate rather than sell' (2009, p 91), and 'Key accounts have multiple relationships' (2009, p 91)'. Smith's article also points to five species of KAM and five lessons in applying KAM. Overall, Smith (2009) suggests that KAM is defined as a long-term, mutually beneficial relationship, one which goes beyond a financial transaction to deliver added value. A PSR who held the title of a key account manager echoed this sentiment of attempting to add value beyond the financial:

When I started in the industry, it was much more of what we'd refer to now as a transactional sell. So, very traditional. I would go in, the healthcare professional would sit in front of me and I would go through this is the disease area, this is the patient, this is what the product does, this is what's different about us. Very much one way, getting the message to the healthcare professional ... Today, it's much more kind of what we'd call a consultative approach. So, rather than going in with your agenda straight away with this is the disease area I want to talk about, trying to understand firstly from the customer that you're in front of, what's their agenda, what are they trying to achieve and what are they trying to work towards, and what's important to them before you start talking about how you feel you could perhaps support and add value to what they're trying to do. So, it's a lot more integrative in some ways and it's looking for opportunities to work in partnership or work together on a project, normally in an area where the company has obviously got products (Fieldwork Interview, PSR 7).

The described changes to the role in the extract above are in keeping with Smith's (2009) definition of KAM. However, as the informant alluded to, financial value is still

the ultimate aim. Relationship value and collaboration are window dressing for the overall financial agenda.

7.3.3 PSR Attitudes

Earlier, Ashforth's (1999) work on how dirty workers develop a positive professional identity was used to account for changes in PSR job titles. Ashforth (1999) notes that workers in stigmatised professions often develop a strong, positive professional identity. Each PSR I spoke to was proud of the industry they worked in, and, contrary to research in other 'clean' industries, they were pleased with increased regulation.

I think it's really good, I think the industry should be regulated and should be really transparent about what they're doing, and if they are providing education for healthcare professionals then it should be a proper medical speaker who comes in and presents his (sic) own opinion and his (sic) own views, rather than me stood up there talking about a company product, then everybody sits down and has a curry (Fieldwork Interview, PSR 8).

Reputation was frequently cited as a key argument in support of regulation.

Nobody would probably share anything like that (unethical) with me, because I'm a bit of a stickler. Mainly because it's only by being like that that we are going to improve the industry's reputation (Fieldwork Interview, PSR 1).

So, now, even how regulated we are, I think it's good that people see a difference and think "ah, actually this is completely different to how the industry used to be allowed to work." I think it's really good for the reputation of the industry (Fieldwork Interview, PSR 8).

None of the PSRs I interviewed admitted to partaking in any behaviours forbidden by The Code. This, however, does not necessarily indicate that infractions never take place. Due to selection bias, it is wholly possible that only PSRs who felt they behaved in a manner in keeping with The Code would speak to me, or, alternatively, they may not have felt comfortable disclosing any such infractions. Having said this, informants did discuss rumours of infractions by others:

I've heard stories, usually with other companies where you know someone, and some that made the headlines, some companies taking doctors to a blooming strip club or something like that, and, you know, I've heard those kinds of stories, you know, but other than that there might have been like the odd presentation that's got used that's not fully gone through (Fieldwork Interview, PSR 1) Informants referred to their own behaviour as ethical, citing following rules such as The Code as a benchmark, e.g. 'I've always been really ethical and followed any rules' (PSR 1). Regulation was consistently pointed to as evidence of the industry's new 'goodness.'

7.3.4 Discussion: The verdict

A long tradition of critical literature exists that presents PSRs as unethical manipulators, who use gifts and personality typing to covertly influence healthcare professionals into doing their bidding. Indeed, PSRs still engage in personality typing (although an informant assured that 'it's not in a manipulative way'...). However, in other areas which have been criticised, such as gift giving and provision of hospitality, the activities of PSRs have become much more regulated. A strategic shift towards patient-focused work and KAM emphasise a de-prioritisation in profit in favour of more noble goals. Changes in regulation and strategy point to an improvement in the ethical standards of the industry, however, as a trainer of PSRs explained, the underlying motivation remains unchanged:

I've had it when a rep said to me "I'm trying to make a difference to people's lives because I'm selling an antidepressant." I said, well, hang on a minute you're working for a company that sells a product for shareholders and has to make a profit. Your product is the same as Kellogg's selling cornflakes. It's just that you're bound by more regulation and have to do it in a slightly more ethical way. But it's still a product, and you still have shareholders, and you mustn't forget that, you know' (Fieldwork Interview, Pharmacist 8).

As noted in the extract above, antidepressant manufacturers are accountable to their shareholders. They are guided by 'the invisible hand' to maximise profits, and changes in regulation and strategy both serve to support this underlying motive. The ABPI prioritise the reputation of the industry to the extent that discrediting the industry is a breach of The Code punishable by the PCMPA. Abraham (2008) refers to this regulatory phenomenon as 'neo-liberal corporate bias'. Self-regulation by corporations, such as is the case in the pharmaceutical industry, leads to a self-serving regulatory structure which only enacts rules which benefit the industry. In the case of PSRs, they have been regulated away from the parodied image of them as manipulators precisely due to this criticism and the harm that it did to the industry's

reputation. Recent years have signalled an increase in regulation pertaining to those activities where PSRs intersect with industry outsiders, such as healthcare professionals. However, activities which are unseen by outsiders remain unregulated, such as the use personality typing. Another example of this is the lack of regulation over targeting and bonuses.

Targets

Each informant spoke of targets they were given. Targets came in many forms, including the number of prescriptions, number of individual calls, number of healthcare professionals contacted, and number of formularies accessed. Targets changed depending on the job.

As a hospital representative, I would have been targeted on things like how many formularies I could get the product on. That was kind of my aim (Fieldwork Interview, PSR 8)

Informants reported that targets were generally achievable simply by 'doing the job' (PSR 1), and thus did not require them to be overly competitive or engage in unethical behaviour to achieve. The only informant across the interviews who reported questionable behaviour in relation to PSRs was a pharmacist, who said they were sometimes asked to make their orders for generic medications slightly earlier or later depending on the timeframe of the PSRs target.

Additionally, PSRs who perform well may also receive awards at annual ceremonies, as well as prizes and bonuses. The only mention of targets in the 2016 ABPI pertains to how often a PSR can visit a healthcare professional:

When briefing representatives, companies should distinguish clearly between expected call rates and expected contact rates. Contacts include those at group meetings, visits requested by doctors or other prescribers, visits in response to specific enquiries and visits to follow up adverse reaction reports. Targets must be realistic and not such that representatives breach the Code in order to meet them. (ABPI 2016:23)

The rationale underlying this portion of The Code appears to be that, if PSRs were to call on individuals too often, then it could be inconvenient for a healthcare professional. The Code therefore states that, unless requested by the healthcare professional, individual calls to a healthcare professional should not exceed three annually. There

is no specified number around the maximum 'contacts' permitted. Indeed, the sales and formulary targets mentioned by informants do not appear in The Code. Moreover, The Code offers no guidance on the incentives to be offered to PSRs for attaining their targets.

Incentives for individuals working in the financial services have been heavily scrutinised and regulated in response to the scandals surrounding the financial crisis. However, there has yet to be a similar level of public scrutiny over incentives for PSRs. Although job listings for PSR roles advertise bonuses, I have been unable to gather exact information about the size of bonuses that PSRs may expect. One hint in this direction comes from a complaint logged to the PCMPA about a healthcare professional who went on a Caribbean holiday awarded to her PSR husband. The husband was awarded the trip along with a 'significantly increased cash incentive' after exceeding a sales target for a drug used at his wife's hospital. In this case, the PCMPA (2011) ruled that The Code had not been breached.

Once again, this supports Abraham's (2008) notion that pharmaceutical industry regulation is influenced by 'neo-liberal corporate bias.' There has yet to be a scandal over the use of incentives to motivate PSRs, and, consequently, there is no financial incentive for the industry to increase its regulation of targets or bonuses. The current regulation for bonuses is as follows: '15.7 Representatives must be paid a fixed basic salary and any addition proportional to sales of medicines must not constitute an undue proportion of their remuneration' (ABPI 2016, p. 22). It is not specified what is meant by 'undue proportion'.

Bonuses in the financial services were deemed unethical in that they motivated employees to push products on customers for whom the product may not have been suitable. In the pharmaceutical industry, the sales of a drug should be limited to the number of people who have the condition and could realistically benefit from using that drug. For antidepressants, sales should thus be limited to the population of people who have a condition that the drugs can treat. However, the socially constructed, elastic nature of diagnoses complicates this issue further. Whether bonuses have the potential to encourage PSRs to aggressively promote their product in such a way that sales might exceed the population of patients who may benefit, is, ultimately, unclear due to the lack of transparency surrounding bonuses.

7.4 Conclusion

Because of increasingly stringent regulation on the behalf of the ABPI, PSRs no longer partake in the marketing activities which have been subject to ethical criticism. Giftgiving in the form of pens, stationary and such like has been banned by the ABPI. Furthermore, the hospitality PSRs were previously able to offer healthcare professionals has significantly reduced in its luxuriousness.

As with the changes observed in other chapters, improving the reputation of the pharmaceutical industry appears to be the principal motive driving these changes in operations. Pharmaceutical companies' desire to distance themselves from the parodied image they acquired in the 1990s is evident in the job titles of salesforce employees. Hospital specialists, key account managers, amongst many others, stand-in for the contemporary, penless versions of PSRs.

The regulatory changes enacted by the ABPI have been welcomed and go some way to reducing the ability of PSRs to influence prescribers based on 'reciprocity norms' (Martin 2006). Furthermore, criticism of industry practices, and the work of investigative journalists in exposing these scandals, have thus made it profitable for the industry to adopt a more ethical marketing strategy. However, this success demonstrates that allowing the industry to self-regulate in this manner means that only observable, publicly criticised activities become regulated. This supports Abraham's (2008) characterisation of pharmaceutical regulation as driven by 'neo-liberal corporate bias'. That is to say, regulation is driven by the interests of the industry, rather than the public interest. The onus is thus placed on journalists and academics to examine industry practices and campaign for change when objectionable activities are uncovered. This reactive regulation can be slow, as demonstrated by the length of time it took for gift-giving to be banned by the ABPI. However, until pharmaceutical marketing is regulated independently of the industry, this will likely remain the case.

Part 4: Covert Target Marketing: Gatekeepers and Opinion Formers

8: The Healthcare Professionals

8.1 Introduction

In the UK, it is illegal to advertise prescription medications directly to the public. Therefore, pharmaceutical companies must target different points in the supply-chain to increase sales of their drug. Healthcare professionals are the primary target of antidepressant marketing messages due to the prescription-only status of the medications. Pharmaceutical companies also collaborate with charities to increase demand for their products by increasing awareness about the condition the product treats. This section looks at the targets of antidepressant marketing efforts. Firstly, this chapter examines the role of healthcare professionals and their complex relationship with companies. The following chapter focuses on disease awareness campaigns, arguing that, whilst these have been co-opted by companies to promote marketing messages, more recent campaigns have included less disease mongering.

In addition to being the targets of the pharmaceutical industry, healthcare professionals are also its paid collaborators and advisors. However, this distinction is often a blurry one. Critics argue that any contact with the pharmaceutical industry has the potential to influence attitudes towards a specific drug and, ultimately, even in relation to prescribing. Therefore, even whilst working on behalf of the pharmaceutical industry, they may also be subject to marketing messages. Whilst this is a compelling argument that will be explored in this chapter, the phenomenon of healthcare professionals receiving funds from pharmaceutical companies will be discussed separately from the discussion of healthcare professionals as consumers of marketing materials. This separation is a practical one, which allows for a better exploration of the issue of healthcare professionals being paid by pharmaceutical companies, rather than acting as a statement on the nature of these interactions.

This chapter investigates the ongoing and ever evolving relationship between healthcare professionals and Big Pharma antidepressant manufacturers, through focusing primarily on three kinds of healthcare professionals: GPs, Psychiatrists and Pharmacists. Firstly, the roles of healthcare professionals in the antidepressant supply-chain will be presented, with particular reference to both how this influences the extent to which they are targets of marketing messages and how they manage this. Secondly, I focus on interviews with informants who have received thousands (in some instances hundreds of thousands) of pounds in exchange for consultancy work. I present their experiences and examine their motives in relation to existing literature on the ethics of pharmaceutical collaboration. I then explore the role played by antidepressant manufacturers in educating healthcare professionals, ultimately characterising this as a no-win situation.

8.2 The Gatekeepers

All antidepressants produced by the pharmaceutical industry are classified in the UK as prescription-only. Resultantly, the drugs can only be legally obtained under the authorisation of a sufficiently qualified medical professional and cannot be sold directly to patients. Therefore, as is the case with antibiotics and asthma inhalers, if you require a SSRI, you first need a prescription from a medical professional. This places healthcare professionals in an integral position in the antidepressant supply-chain. They are the gatekeepers of medical resources and therefore a valuable target audience for antidepressant marketing efforts. In this section, I focus on interviews with healthcare professionals most involved in gatekeeping: GPs, psychiatrists and pharmacists.

In addition to acting as an intermediary between Big Pharma and patients on a caseby-case basis every time they encounter a patient, healthcare professionals also act as gatekeepers on a more macro level. Very senior healthcare professionals work with NICE to decide whether a medication should be granted marketing authorisation, and in what circumstances it should be recommended. Furthermore, on a local level healthcare professionals are involved in deciding which medications should be included on the formulary (a list of drugs from which practitioners are advised to or allowed to prescribe). The term 'postcode lottery' is used to describe the different healthcare provisions available in different areas. The decision about whether to include a drug on the formulary is complex, and sometimes requires decision-makers to assess conflicting evidence over the safety, efficacy and cost-effectiveness of a medication, as well as patient accounts about the impact their condition has on their lives. Again, healthcare professionals act as the gatekeepers here. In the postcode lottery they are Camelot, selecting the numbers which may (or may not) appear on your ticket.

Healthcare professionals occupy a trifecta of gatekeeper roles: on a macro level via granting marketing authorisation; on a meso level via curating formularies; and on a micro level via writing prescriptions. For medications where there is a generic alternative, pharmacists occupy a forth gatekeeping role via deciding which brand of medication should be dispensed. Before an antidepressant reaches a patient, it must overcome at least three hurdles guarded by healthcare professionals. Healthcare professionals are therefore at the centre of antidepressant manufacturers' marketing strategies. However, in a post Bad Pharma (Goldacre 2012) society, the access companies have to gatekeepers is changing, which is the focus of this chapter.

The following section explores healthcare professionals' roles as decision-makers in the antidepressant supply-chain and their experiences as the targets of antidepressant marketing campaigns. The chapter demonstrates that healthcare professionals occupy diverse roles in their relationship with pharmaceutical companies, and presents findings for each of these professions in turn, before, finally, exploring how these findings relate to existing regulation.

8.2.1 General Practitioners (GPs)

As the first port of call for most individuals when accessing healthcare services, GPs are responsible for diagnosing the majority of cases of depression, and, hence, prescribe the most antidepressants. Every GP interviewed reported using the local formulary and NICE guidelines when deciding what antidepressant to prescribe, in addition to their personal experience.

GPs reported less interaction with the pharmaceutical industry than psychiatrists. Although I interviewed fewer GPs than psychiatrists (5 GPs vs. 10 psychiatrists), this finding was supported by my interviews with pharmaceutical industry employees.

I've not actually had any interaction with anyone (from the pharmaceutical industry) regarding depression. I think that's probably more psychiatrists than GPs, trying to appeal to them (Fieldwork Interview, GP 2)

It's been a long time since l've seen anyone or anyone's even asked! (Fieldwork Interview, GP 1)

One GP informant did report seeing a PSR. For this doctor, PSRs were their only source of information on new drugs.

I see a drug rep, so I can practice my critical appraisal skills. They'll all say they're the best. They'll say it's not addictive but that's just because there's no data to say it's not addictive, not because there's evidence to show that it's not addictive. They'll show it has a favourable side-effect profile, but that's just because the patients haven't mentioned side-effects (Fieldwork Interview, GP 3)

Interestingly, although this GP had contact with key account managers about new treatments, they reported not prescribing any on patent antidepressants. In addition to being aware of new drug treatments, this GP was well-informed of non-drug treatments. This GP was also the only healthcare professional I spoke to who, without prompt, spoke about offering computerised CBT, which is a first-line option recommended by NICE.

Overall, GPs described treating depression as relatively routine and formulaic. Each GP had preferences based on personal experience about which SSRI to prescribe first, but otherwise followed NICE guidelines in a similar way. If a patient had not responded by a third-line treatment, ordinarily involving another off-patent antidepressant with a different treatment mechanism, then the patient would be referred to a psychiatrist. This finding conflicts with larger sample surveys studying GPs adherence to NICE guidelines for the treatment of depression (Toner et al. 2010; Herzog et al. 2017). Such studies find that GPs do not always follow NICE guidelines, particularly in relation to changing the dosage of an antidepressant, or changing to a different antidepressant if the patient is not responding to treatment. In these studies, GPs report treating depression less rigorously than the recommendations by NICE. It is therefore possible that my sample is biased, due to the fact that only those GPs who felt confident that they were treating depression according to guidelines agreed to be interviewed.

8.2.2 Psychiatrists

Those individuals referred to psychiatrists tend to either have very severe depression, treatment resistant depression or other co-morbid (co-occurring) mental health

conditions. Psychiatrists have more freedom in prescribing newer antidepressants than GPs, due to the more specialist patients they see. Therefore, they represent a more lucrative target for pharmaceutical marketing. Indeed, one psychiatrist I interviewed turned up with a Lundbeck lanyard around their neck (Lundbeck are currently actively marketing the antidepressant, Brintellix). Of the healthcare professionals I interviewed, psychiatrists reported the most contact with PSRs.

They sometimes call a secretary and book an appointment to come and see me or a colleague, and they'll have 15-20 minutes and they'll give us refreshments, tell us about new products (Fieldwork Interview, Psychiatrist 4).

Although they received more attention from the industry and were more likely to agree to meet with PSRs, psychiatrists described being wary about the fact that the information they received was underpinned by marketing motives.

I try to take what they say with a pinch of salt, although it's interesting ... it's kind of marketing, you have to keep pretty sceptical about what's being said and the motivations for promoting the medications (Fieldwork Interview, Psychiatrist 2)

Although, overall, psychiatrists reported more contact with the pharmaceutical industry, my most critical informant was a psychiatrist who refused contact with the pharmaceutical industry:

I like tried and tested and I like a good evidence-base ... and I don't mean, you know, look at this graph, that line goes up and that line goes down therefore this drug is brilliant, and the others are crap. I just don't fall for that. I'm profoundly sceptical ... I've read Ben Goldacre (Fieldwork Interview, Psychiatrist 3)

Overall, psychiatrists reported finding PSRs useful for providing some information on new medications, although they were sceptical about the information they received. The one psychiatrist I spoke to who actively avoided contact with the pharmaceutical industry, spent a lot of time and effort personally researching the data available on new treatments.

8.2.3 Pharmacists

Prior to undertaking this research, I did not realise the vast scope of career options available to pharmacists beyond the local chemist. The tasks undertaken by the pharmacists I interviewed included ordering and dispensing medicines, engaging with patients, changing medications, diagnosing, prescribing, advising doctors, researching prescribing patterns in marginalised communities, deciding what should be allowed on formularies, deciding what drugs should be approved, not to mention frequently making life-or-death decisions about what medicines the NHS should fund. Pharmacists proved to be particularly integral to the prescription of generic medications.

In terms of contact with the pharmaceutical industry, the pharmacists interviewed did not report seeing PSRs often. Most PSRs work on newer drugs which are still on patent. Consequently, pharmacists do not have the option of switching to a generic medication and instead must dispense the branded version. The lack of input of nonprescribing pharmacists in this process means they are not hugely desirable to PSRs working on branded drugs.

The exceptions to this trend are more senior pharmacists who have additional decision-making roles, such as contributing to local formularies, NICE guidelines, and so on. One pharmacist that I interviewed had previously been responsible for deciding what medicines should be provided for by their health board. New medicines are expensive and so it is often down to the health board, trust, or clinical commissioning group to decide whether to pay for a drug. We hear about this most often in media discussions about the 'postcode lottery'. The pharmacist I spoke to had to consider the price of the drug, the burden of the disease, the efficacy of the drug, and the experiences of people with the condition to decide whether to fund the treatment. I asked whether they had contact with the pharmaceutical industry as part of this role:

Yes, yes, I had representatives coming to see me. I thought about whether that was appropriate or ethical or not and I decided I would rather meet them to understand their marketing strategies, because I knew they had access to our prescribers in the community ... some of my colleagues would not see industry representatives at all, because they felt that it was a conflict of interest and unethical, and I took a different view (Fieldwork Interview, Pharmacist 3).

As aforementioned, one pharmacist I interviewed even reported being recruited to work for an antidepressant manufacturer whilst working as a pharmacist on a health board. Pharmacists are also often key decision-makers when it comes to generic medications. Pharmacists are incentivised to prescribe the cheapest possible generic drug via a system which allows them to keep a portion of the money saved against the drugs budget. This incentive encourages pharmacists to 'shop around' to find the cheapest generic drug. However, there is also an incentive to keep to the same generic drug, even if a cheaper option is available. Although the active ingredient is the same in all generic versions of a medicine, the size, colour, and shape may differ. These changes can cause confusion in older patients or patients with learning disabilities, thus compromising patient safety. Moreover, changes in medication appearance can cause anxiety and produce a different placebo response to the medication. One community pharmacist noted that, if they were to frequently change generic providers, they may lose customers who could simply go to the pharmacist five minutes down the road to get the generic drug they had previously been getting.

Due to the decision-making power community pharmacists have over generic prescriptions, PSRs from generic companies sometimes visit.

They may well come once a month and, say, go through the order and say, 'okay, what do you need this month, is there anything else I can give you?' Sometimes it's on spec, and they'll just call in and say 'l've got a good deal on this that or the other' (Fieldwork Interview, Pharmacist 5).

Generic PSRs operate differently from their counterparts working on branded medications. Generic sales representatives often sell all the drugs a company offers, rather than one or two as is the case with branded medicines. They also have far smaller budgets and tend to have more of a supplier relationship with community pharmacists, capitalising on existing demand and competing on price, rather than, say, trying to generate demand for a new compound as is done by PSRs with branded medicines.

Overall, pharmacists form an integral and complex part of the antidepressant approval, research, marketing, prescription and dispensation process. Each of these roles leads to different interactions with the pharmaceutical industry.

8.3 From Gatekeepers to Locksmiths

In 2003, the British Medical Journal (BMJ) published an iconic illustration on its cover, depicting cartoon pigs drinking wine, eating expensive looking food, playing golf and

delivering presentations, all while lizards in suits greedily watch them – see Figure 5. The title read 'Time to untangle doctors from drug companies' (BMJ 2003). In addition to being the targets of the pharmaceutical industry's covert marketing activities, healthcare professionals are also its paid collaborators and advisors. This distinction, however, is a blurry one. Critics argue that any contact with the pharmaceutical industry has the potential to influence attitudes towards a specific drug and, ultimately, in terms of prescribing (e.g. Wazana 2000). Therefore, even whilst working on behalf of the pharmaceutical industry, they may still be subject to marketing messages.

Figure 5: BMJ (2003)



On the 30th June 2016, the ABPI published a list on their website titled 'Disclosure UK'. The list contains information on payments received by healthcare professionals from pharmaceutical companies. With 50,2083 entries on Disclosure UK amounting to

364 million pounds, the extent to which doctors have been 'untangled' from drug companies over the last fifteen years is open to debate.

This section presents the findings of in-depth interviews with ten individuals on the Disclosure UK list. Of the healthcare professionals interviewed, six were psychiatrists, two pharmacists, one a neuroscientist and a healthcare economist. Disclosure UK has been analysed using quantitative methods by the BMJ. This analysis is crucial for providing a digestible snapshot of the contents of the database. However, this qualitative investigation represents the first attempt to go beyond these figures to understand the motives and experiences of healthcare professionals on the industry's payroll.

8.3.1 History: Drug-fuelled hedonism

This section begins by presenting a historical account of healthcare professionals' experiences collaborating with the industry prior to (and in some ways contributing to) the BMJs call to untangle. The discussion is then brought into the present with an indepth examination of the nature of this modern collaboration. Ultimately, this section presents the argument that, whilst doctors have yet to 'untangle' from Big Pharma, the way in which they interact with pharmaceutical companies has changed for the better due to increased transparency.

The relationships between healthcare professionals and PSRs has received the Hollywood treatment, in films such as Side-Effects and Love and Other Drugs. These films present the pharmaceutical industry as sexy and manipulative, in addition to having undue influence over healthcare professionals. Non-fiction books and academic literature have supported this popular image of pharmaceutical companies using money and gifts to bribe healthcare professionals to do their bidding (e.g. Goldacre 2012; Healy 2006).

Four of my healthcare professional informants had collaborated with antidepressant manufacturers during the late 1980s and 1990s, during the time in which many of the blockbuster drugs were launched. Each confirmed that the popular depiction of Big

Pharma companies as being lavish with their gift-giving and flying people to exotic destinations for meetings was true at this time.

I think 20 years ago some of the things that the companies did in terms of entertainment and remuneration, etc., you know, they were clearly very questionable. And I think that some of the concerns that have been raised about uh, NHS clinicians and academics interacting with industry have been very well made, and I think tying up some of the regulations have massively improved things. I mean sometimes some of the entertainment when you went to an ad board was lavish in the extreme. And it was completely and utterly unnecessary (Fieldwork Interview, Psychiatrist 9).

Informants spoke at length, often with fondness, about their lifestyles in the 1980s and 1990s. Their accounts support the caricature depicted the cover of the May 2003 issue of the BMJ in uncanny detail.

Go back 20 years and if you were at an important advisory board or an international board, I remember going to one at a beautiful island on the great barrier reef and we were flown to Melbourne and then flown on there, and we were staying in a hotel that was normally only populated by film stars. Uh, so, it was quite ... apart from doing the work, it was quite a nice lifestyle. People enjoyed doing it because the companies made a fuss of them and this was at a time when even the, sort of, all the meetings, the launch meetings with consultants and junior doctors and people could happen abroad and were in fairly lavish hotels (Fieldwork Interview, Psychiatrist 6).

The conflicts of interest which arise when healthcare professionals receive funds from pharmaceutical companies have been extensively documented. Payments influence prescribing (Wazana 2000) and bias the results of research (Lexchin et al. 2003). As discussed in the previous chapter, gifts and hospitality can also trigger 'reciprocity norms' (Katz et al. 2010). Healthcare professionals can subconsciously feel obliged to behave in a way which favours those who have compensated them. Although healthcare professionals are aware of the potential for a conflict of interest, they do not believe that they themselves are biased (e.g. Rutledge et al. 2003). Again, corporations are legally-bound to prioritise generating a return on the investment of their shareholders. Indeed, if healthcare professionals were impervious to the influence of pharmaceutical companies, then prescription patterns would be similar for healthcare professionals who co-operate with the pharmaceutical industry and those who do not. Instead, researchers such as Muikers et al. (2005) show that 'pharma

friendly' (PSR 1) healthcare professionals have more expensive and less efficacious prescribing patterns than their more hostile counterparts.

Each informant that was interviewed as part of this investigative social science approach, and who had worked during the blockbuster era, noted that, whilst companies had 'spoiled' them in the past with luxury and excess, this popular image of pharmaceutical industry interactions was now out-dated. Instead, they noted that regulation and reputation preserving sentiments had steered companies away from the grandeur of golf courses and five-star hotels towards more down-to-earth accommodation.

Personally, I think it's gone slightly, maybe only slightly, but slightly too far in the opposite direction. There are times when companies are saying, "well, we can't put you up at that hotel, we've got to put you up at this one because we don't want to be seen to be overly influencing you". And their sort of threshold is we won't pay for you to go and stay in any hotel that would be better than one you would pay for yourself. Well there's plenty of hotels I've been put up by companies there's no way on earth I would have paid for that myself. I wouldn't, you know, they were horrible hotels and I wouldn't have gone there, but, you know, it's probably better to err on that side than on the side of being over lavish (Fieldwork Interview, Psychiatrist 9).

All that's changed radically. Everything's done on a shoestring and not just because they don't have as much money, but because of the pressure on drug costs and also just because it's not seen as good (Fieldwork Interview, Psychiatrist 6).

The ABPI code of practice now condemns 'excessive hospitality', which they define as facilities that are so lavish that the meeting or conference becomes secondary (ABPI 2016). This change coincides with the banning of small gift-giving. Both of these practices have been publicly, most notably in Goldacre's (2012) Bad Pharma, criticised due to their propensity to bias healthcare professionals.

This shift away from activities which have been publicly denounced as unethical is a conscious one. In the previous chapter, the pharmaceutical industry employees emphasised the importance of improving and preserving the reputation of the industry in the wake of scandals. However, scandals, such as the 'Seroxat Scandal' discussed in Chapter 5, have undoubtedly damaged the reputation and therefore the profitability of the industry. Resultantly, companies are improving their ethical standards to protect

and improve their reputations. However, profit is still the principal motivation of pharmaceutical companies, as I show below when exploring the role of pharma money in persuading professional gatekeepers to continue opening their doors to drug solutions.

8.3.2 Pharma Money for Professional Judgement

The previous section demonstrated that the way healthcare professionals are incentivised to, and compensated for, interacting with industry has changed. There has been increasing regulation of healthcare professional/industry relationships, however, as exemplified by Disclosure UK, pharmaceutical companies still pay hundreds of millions of pounds each year to healthcare professionals and the organisations they work for. This section examines the motivations and experiences of healthcare professionals who received money from an antidepressant manufacturer in 2015. The term 'Dark Money' has been used to describe the power and influence that money has in the realm of politics (Mayer 2016). Throughout this section, the term 'pharma money' will be used, partly as shorthand for more cumbersome phrases, but also to emphasise the power and influence wielded by such money.

The collaboration between healthcare professionals and pharmaceutical companies is a complex and contentious subject, due, in part, to the conflict of interest it gives rise to. We would expect healthcare professionals to behave in a manner which prioritises patient outcomes, but, conversely, pharmaceutical corporations are structured to prioritise profits, in a way that, according to Bakan (2012), renders them psychopathic. The two principal ways that healthcare professionals receive pharma money are via advisory boards and speaker meetings. Eight of my informants had been paid by pharmaceutical companies to partake in advisory boards. Since both advisory boards and speaker meetings are reserved for academic healthcare professionals at the forefront of their field, there is significant overlap between these two groups of collaborators. Everyone I spoke to who had taken part in advisory boards had also spoken at meetings paid for by pharma money. One younger psychiatrist had spoken at meetings, but not taken part in advisory boards. Healthcare professionals who undertake either or both of these kinds of collaboration are referred to in the industry as KOLs.
Advisory boards (commonly referred to as ad boards) comprise panels of around eight academics/healthcare professionals who give their expert-opinion on various aspects of a drug's development. These are healthcare professionals from a variety of disciplines who are well-respected within their field, and who have a good relationship with pharmaceutical companies. The decisions they advise on can include advice about what research methods to use in a clinical trial, how best to present trial data, and what marketing messages the company should focus on. They often take place at varying intervals over the course of several years, and the same healthcare professionals are usually present throughout the entire ad board process, albeit some may leave due to retirement or other work commitments.

The company people sit in the background and take copious notes, and it's run by a chairman who's usually one of the academics who all of the others trust (Fieldwork Interview, Psychiatrist 6).

Speaker meetings generally refer to occasions on which a healthcare professional is paid by a company to do a presentation. Often the presentation will include slides, which are thoroughly vetted by the pharmaceutical company to ensure that all claims are evidence-based, that are developed by either the pharmaceutical company or created by the speaker themselves. These speaker meetings are ordinarily described as educational and tend to focus on disease areas, rather than merely the specific company drug. At speaker meetings, healthcare professionals often present to other healthcare professionals. The issue of healthcare professionals thus being recipients of pharmaceutical industry funded education is explored in a later section. In this section, I present the findings of my investigation into the phenomenon of healthcare professionals collaborating with antidepressant manufacturers.

The popular depiction of healthcare professionals' motivations for interacting with the pharmaceutical industry is greed. This is exemplified by the use of chubby pigs to represent healthcare professionals in the iconic BMJ cover – see Figure 5. Many of the informants I spoke to were listed as receiving thousands (even tens of thousands) of pounds from pharmaceutical companies. I was therefore interested in the extent to which informants were motivated to collaborate with industry by the financial benefits. However, the accuracy of the figures listed in the database compared to the amount

of money that individuals ultimately received varied. Sometimes, money went to the organisation the individual worked for as opposed to directly to the individual, even though they were listed as the recipient, and despite the fact that universities and health boards can themselves be named on the database.

You were able to find me through the disclosure of income. Now what that doesn't do is, it doesn't say where that money goes, it just assumes it's going to me. 90, 95 per cent of the income I get through doing this sort of work goes into a university account. It does not come to me, personally. So, what it does is, it actually facilitates some of the research I do. It doesn't personally benefit me in any way, in any pecuniary way (Fieldwork Interview, Psychiatrist 9).

Furthermore, in answer to the question of what motivated their collaboration with industry, each informant that I had contacted via Disclosure UK claimed that the money was not a large factor in their decision-making. Each informant who regularly partook in such work was already well-paid from other work. Without prompting, two informants told me that they no longer needed to work for financial reasons and that they could afford to comfortably retire, but nevertheless chose to continue working.

Contrary to the greedy pigs cartoon, then, which depcits healthcare professionals interacting with industry for financial gain, every informant highlighted that their main motivation for collaborating with industry was to gain knowledge.

It's basically learning. I mean, I don't need to work, I'm past retirement age. I just enjoy it very much. Obviously, the money's quite nice, but I don't ask a huge fee, I just enjoy the work ... It gave me a better understanding of clinical trials. It gave me a much better understanding of marketing. A better understanding of marketing material, how it can be sometimes less than obviously truthful, if you see what I mean. Um, how they use particular images to give particular impressions and how in the university it helped me teach really, because I was able to teach what I learned in terms of trying to engender a more collaborative attitude amongst other pharmacists, how to look at clinical trial material, and how to review papers to do critical appraisals (Fieldwork Interview, Pharmacist 7).

The fact I've been able to get extra information because of going to that ad board just puts me further ahead of the curve. If I hadn't gone to that ad board, I'd have still had to find all that information out and it would have taken much longer ... one advantage of going to an ad board where you've got other KOLs is you can go, hold on, that doesn't look right, and another KOL goes, no, it does, that's absolutely fine ... You can see if your view of the data is something that others would share or whether you've completely misinterpreted the data. If you're sitting in an office by yourself, you just had to entirely trust your own reading of the data (Fieldwork Interview, Psychiatrist 9).

These healthcare professionals argue that they gain knowledge when attending multidisciplinary forums. Indeed, this argument is supported by the work of organisational researchers Randall and Munro (2006). They observed knowledge sharing when studying forums between groups of mental health professionals across different sectors. Subsequent to emphasising how the opportunity to learn motivated them to partake in such work, each respondent mentioned how the information learned, particularly in ad boards, was shared amongst their institutions (Funding for educating healthcare professionals is waning in many areas as I discuss later in this chapter). A further motivation, closely linked to learning, is early access to data.

It's a way of knowing what's coming before it arrives ... I also like having access to all the data. I like the privilege of having access to the data that, for example, [COMPANY NAME] wouldn't give NICE. I've seen all of that and it's confidential, but it allows you to understand why claims are made (Fieldwork Interview, Psychiatrist 6).

I get the best opportunity to see the full data set of a new medication ... A lot of the data wouldn't be (publicly) available, so I'm able to be at the forefront of my field (Fieldwork Interview, Psychiatrist 9).

The availability of trial data is an ongoing hotly contested issue. Indeed, the Seroxat scandal was largely a result of hiding data which reflected negatively on the drug. The drug was therefore prescribed to adolescents as a safe medication, even though data suggested it caused suicidal behaviour. Critics of the industry, led by Ben Goldacre, are now campaigning for all trial data to be publicly released (AllTrials.net 2018). Whilst the AllTrials movement has made some headway, they have yet to reach their ultimate goal. Therefore, ad boards represent the only opportunity I have identified where healthcare professionals get to see the full data set for a new medication.

The privilege of early access to data is likely to be personally rewarding, and, indeed, healthcare professionals may feel special or important by viewing such privileged information. However, there are noble benefits of accessing full datasets. One psychiatrist I interviewed specialised in very unwell patients with treatment resistant depression. These patients have tried multiple treatments without improvement, and so are likely to be the first patients to be prescribed new antidepressants. By viewing

the full dataset, my informant emphasised that they were able to be on the cutting edge of new treatments that could potentially help their most difficult to treat patients. Indeed, the idea that collaborating with the pharmaceutical industry could ultimately improve patient outcomes was a popular one in the interviews. As mentioned previously, some healthcare professionals felt that, by sharing the insider knowledge they gained from pharmaceutical companies with colleagues, they could improve the lives of more patients. Moreover, healthcare professionals acknowledged that it was only through working with the industry that they had any capacity to change it, and, in turn, improve it for patients:

I feel very, very, strongly that it is important that there is constructive engagement with the pharmaceutical industry by clinical academics and leading clinicians. I think without that we have no possibility of being able to influence what industry does, and if we are not able to influence it in any shape or form that is to the detriment of our patients (Fieldwork Interview, Psychiatrist 9).

It's not work that I do because I have some messianic urge to work with drug companies. It's worked that I do because it seems to me to be reasonable and ethical, and it seems to me that I may have an opinion that is useful in shaping what happens (Fieldwork Interview, Psychiatrist 8).

Relationships were cited by all informants as an important factor in motivating their collaboration with antidepressant manufacturers. Healthcare professionals involved in collaborative activities such as ad boards were generally of high-status and well-established. Collaboration with industry thus provided valuable networking opportunities for my informants.

I suppose there's a networking component, it's a way of meeting colleagues in a relatively relaxed setting ... One element of what happens is the companies provide a forum in which academic colleagues meet and discuss and challenge each other (Fieldwork Interview, Psychiatrist 8).

Furthermore, one healthcare professional spoke at length of the relationship they had with the pharmaceutical company. The nature of their experience working with a company dictated whether they would continue their collaborative relationship with the company. On the whole, the informants reported having positive relationships with companies during ad boards. They noted that usually companies seemed genuinely interested in their perspective and expertise, and made changes to their marketing messages in response to their criticisms.

They certainly do seem receptive to criticisms of claims that are unsound that shouldn't be made (Fieldwork Interview, Psychiatrist 8).

I've seen companies where they've attempted to put an unreasonably positive spin on their particular product, and then following feedback from uh, experts, they've gone "oh, right, well we shouldn't really be saying that we can't really justify that", and their marketing message gets significantly toned down and more defensible on the basis of the evidence they hold (Fieldwork Interview, Psychiatrist 9).

Yeah, generally, this sort of expertise is not held in house by any company, so when I have an opportunity to contribute it's obviously scrutinised that I have to justify the position but, largely, the recommendations I made were adhered to (Fieldwork Interview, Psychologist 3).

These accounts of positive experiences of ad boards demonstrate one way in which healthcare professionals can create value for pharmaceutical companies. As discussed throughout this thesis, in the wake of scandal the pharmaceutical industry, especially antidepressant manufacturers, have become increasingly risk-averse. Protecting and improving their reputation is paramount. Through consulting with very senior healthcare professionals, companies are able to prevent disseminating marketing messages which are not sufficiently evidence-based, which, in turn, protects them from scandal. Although informants noted that their recommendations were 'largely' acted upon, they acknowledged that this was not the case in every ad board.

I've been to advisory boards in the past where companies have clearly not wanted to hear what has been said at the advisory board and have got very upset when negative comments have been said. Then one really does wonder what the point of the advisory board was, and then one does start thinking are you just trying to market this drug to a bunch of KOLs and is it nothing other than marketing? I would have to say that's the rarer, more unusual situation (Fieldwork Interview, Psychiatrist 9).

As one can discern in the extract above, the informants noted that there were occasions in which they felt that, rather than providing a service to pharmaceutical companies, they were instead being used as a captive audience to advertise their new drug to. These overt instances were described as rare, but it is wholly possible that, in addition to wanting to gain expertise from KOLs, companies may use ad boards to increase awareness about their new drug among influential healthcare professionals.

Although healthcare professionals continue to receive pharma money, they do so for more complex reasons than those alluded to in existing literature. Rather than being motivated purely by financial greed, healthcare professionals report being incentivised by more intrinsic factors, such as their own curiosity and desire to help patients. Moreover, additional corroboration can be found in the shrinking budgets available to healthcare professionals for continuing professional development (Merrifield 2017). Having said this, this investigation into recent collaborations between industry and healthcare professionals suggests that the two have yet to 'untangle' in the manner proposed by the 2003 BMJ special issue. However, there may be some benefit for patients from this collaboration, as a pharmaceutical industry entirely independent of healthcare professionals would potentially lack specialist knowledge and expertise.

Interview data from respondents who have received pharma money thus support the notion that companies have largely moved beyond the crude disease mongering practices of the 1990s and are increasingly focused on retaining and improving their reputations. Scandals are expensive (The Seroxat Scandal is partly responsible for the largest legal settlement in the industry's history: \$3 billion). Furthermore, investment in services which reduce the likelihood of scandal is fully in keeping with the profit motive. Although this scandal aversion is in many ways increasing the ethicality of industry collaboration with healthcare professionals, the marketing opportunities presented by a room full of influential healthcare professionals has not gone entirely unnoticed. Rather, industry marketing efforts are transitioning, from overt displays of hospitality and overblown claims, to more subtle methods such as continuing professional development.

8.3.3 Pharma Money for continuing professional development.

Healthcare professionals have historically (and still do in some cases) received funds from pharmaceutical companies to partake in educational activities, such as workshops, courses, and conferences. Pharmaceutical industry funded education has been characterised in academic literature as biased and untrustworthy (Takhar et al. 2007; Donnell et al. 2009; Masood et al. 2012). Indeed, to warrant the funding of such education, it is expected that companies must receive some benefit. Hence, a conflict of interest is clearly present when companies pay for the education of healthcare professionals. However, whether this conflict of interest produces a net negative effect is less clear.

Once qualified, healthcare professionals are required to keep their knowledge up-todate by completing continuing professional development (CPD). However, funding, particularly for mental health pharmacists, is scarce. Therefore, the pharmaceutical industry often run training events, and sometimes even pay for conference attendance.

I run training events in my trust for staff and these drug companies they provide speakers who are completely impartial, and they provide training on different aspects of care. So, I already have an acquaintance with them, so they do attend regularly and bring speakers because these are expensive to hire if you work in the NHS, as we get no funding for training at all. Zero. So, whatever you want to do you either ask for the good will of people to come for free, or if you want a speaker who is very well-known and very good in their field a lot of them charge a fee, so the drug reps will sponsor these speakers to come and speak and talk to us and do training (Fieldwork Interview, Pharmacist 8).

Here, healthcare professional informants outline a catch-22 situation, where they had to make a choice between receiving education funded by a biased source or receiving nothing.

The majority, a lot of people in my workplace when they've attended (conferences) it's through this type of funding (pharma) that they've managed to go. Otherwise, nobody would go. Before, our trust used to have a training budget, but we've got nothing now, absolutely nothing. We're not allowed to do anything at all in my trust, it's not the same in every trust, but in my trust, pharmacy department, there's no funding for training ... We don't have anything (Fieldwork Interview, Pharmacist 8).

Consequently, if healthcare professionals declined training from pharmaceutical funders or refused to attend conferences funded by them, then they run the risk of not keeping their knowledge up-to-date to the potential detriment of their patients. If healthcare professionals choose to attend such events they then risk receiving biased information, which could ultimately lead to over-medicalisation, pharmaceuticalisation, and the prescribing of poorly researched drugs, which, in turn, harms patients.

Healthcare professional informants on the receiving end of professional development education funded by pharmaceutical companies played down the risks associated with attending pharmaceutical industry funded training and were keen to emphasise the independence of speakers at these events. One pharmacist noted:

They might bring a speaker to talk about medical legal issues with prescribing, so they'd bring a solicitor and their fees are extortionate and they'll come and talk about your stance as a prescriber. What you should do to protect yourself and make sure your record keeping or whatever. They come and provide that training, so it's good for peoples CPD as well. So, yeah. So, it completely varies, they're not there to promote their drugs because their own regulatory system is very, very strict, and they have to get lots of approvals and their slides, etc., are assessed to make sure nothing in there contravenes with the ABPI code, so they're not doing anything promotional when they come to train people (Fieldwork Interview, Pharmacist 8).

This point was particularly made by individuals who were also involved with the organising of such events, as evidenced by one psychiatrist who was interviewed.

They sometimes arrange free conferences, so they'll do their own meetings and study days which will be free for us to attend and they'll all be sponsored ... they are educational days, but they will call independent speakers and it will be themed around whatever product they've got, so you'll get information about what their new products are but it's not directly. It's not their representative talking about it all the time, independent speakers that're normally called (Fieldwork Interview, Psychiatrist 4).

Most of the healthcare professionals I interviewed who had delivered training funded by pharmaceutical companies supported this view and emphasised their own independence:

I've certainly never felt pressured to say things I didn't want to say, and, no, I can't remember feeling particularly constrained or stopped from saying things that I wanted to say (Fieldwork Interview, Psychiatrist 8).

However, some informants who had themselves presented at such events described

a more conflictual state of affairs. As one psychiatrist observed:

There were times in the past where I was asked to do things that I was very uncomfortable doing. Like, presenting a company's set of data that was entirely created by them and over which I had very little editorial control, and I remember doing that and I didn't realise ... I mean it was a very low-key, local meeting and then I realised that's what they were expecting, they were expecting me to actually act like a trade-rep and I never did that again. I simply said I would not do that (Fieldwork Interview, Psychiatrist 5).

Even those who were confident that their presentations were not unduly influenced by the funding pharmaceutical company, acknowledged that other healthcare professionals may be more malleable. All the informants who collaborated with the industry as speakers at these events were cognisant that their work was of value to the pharmaceutical companies, beyond being simply educational.

I mean they call it non-promotional work, it can never be fully non-promotional (Fieldwork Interview, Psychiatrist 9).

The idea of educational presentations and events as being 'non-promotional' was also challenged by the following healthcare professional who likened their work to advertising.

You would point out the advantages as well as the disadvantages of their product and compare their product to other products available. Just like TV advertising or TV programs. You know, there are other similar products available. You have to be fair. And to be credible, you see. To be credible, and to be a potential useful individual from the company's point of view and to the audiences' point of view, you have to be seen to be totally impartial as well as credible (Fieldwork Interview, Pharmacist 7).

With the NHS under increasing strain, training budgets are being cut. Health Education England is the executive non-departmental public body responsible for the training and development of the NHS workforce. In their 2015-16 budget, they allocated £205 million to 'workforce development', a fund predominantly used for CPD training. For 2016-17, this figure was nearly halved to £104.3 million (Merrifield 2017). Many healthcare professionals are therefore left to choose between potentially biased education paid for by pharma money, no continuing medical education, or paying for their education out of their own pockets. Recipients of pharma-funded education characterise it as unbiased and evidence-based, perhaps to mitigate their own cognitive dissonance. However, those who deliver such educational programs present a more nuanced view that suggests that, whilst regulation is increasing, if such education is to be funded by pharma money then it must have some benefit to the company.

8.4 Over the Influence?

In line with the trend in industry collaboration with charitable organisations, collaboration with healthcare professionals has undergone ethical improvements. Again, the desire to improve the reputation of the industry in the wake of scandals and criticism has played a key role. Informants noted that companies have become much more prudent and risk-averse in their dealings with healthcare professionals.

I do think some of the activities in the past and some of the activities of my colleagues in the past was, um, unreasonable, potentially unethical, but I do believe we are in an era where that has changed substantially and I think that it is much harder, though not impossible, for people, companies and academics, clinicians like myself to behave in inappropriate ways. It's much harder for that (Fieldwork Interview, Psychiatrist 8).

My informants noted no breaches (or attempted breaches) of the ABPI code of practice. Rather, companies were anxious to meet and exceed regulatory requirements in this area. Furthermore, the informants noted that they had been encouraged by companies to disclose the information about their payments on Disclosure UK, with some companies even now refusing to work with individuals who are not willing to be transparent about their payments.

It is important to note, however, that I was only able to interview industry collaborators who actively disclosed their payments on Disclosure UK. Therefore, it is possible that those who chose to have their information withheld from the list would not report the same dedication to transparency within the industry. The BMJs analysis of Disclosure UK found that 70 per cent of healthcare professionals chose to fully disclose their payments (BMJ 2016). Whilst this number may appear high, the 30 per cent of healthcare professionals who did not disclose received over half of the total value of payments. This means that the healthcare professionals who were paid the most were less likely to disclose. Consequently, further research needs to be done into these undisclosed interactions between healthcare professionals and antidepressant manufacturers.

For each of the professional representatives that were interviewed, there were some who avoided contact with the pharmaceutical industry due to a perceived conflict of interest. PSR informants noted that this is an increasingly popular stance, especially in light of the popularity of Goldacre's (2012) 'Bad Pharma'. However, when considering whether it is possible for healthcare professionals to completely shelter themselves from pharmaceutical industry messages, there are clear chinks in the armour.

I tend to say I prescribe what I have to prescribe to each patient. However, at the end of the day, we shouldn't forget that all of our recommendations which are based on NICE guidelines, which are based on RCTs, which are funded by pharma companies. So, regardless of whether or not you have attended a conference sponsored by a pharma company, or regardless of whether or not you've given a lecture which has been funded by a pharma company, to a large degree all of our recommendations in our practice are funded by pharma companies (Fieldwork Interview, Psychiatrist 7).

Both GPs and psychiatrists reported using the Diagnostic and Statistical Manual 5 (DSM-V) and the International Statistical Classification of Diseases and Related Health Problems 10 (ICD-10), with the DSM-V being the vastly more popular choice. The DSM-V, in particular, has been criticised for allowing pharmaceutical companies, and those with financial links to the companies, to sit in on decision-making panels and influence diagnostic criteria (Cosgrove and Krimsky 2012). More recently, pharmaceutical companies were blamed for the removal of a bereavement exception, which stated that if a grieving person was experiencing depressive symptoms that this was a normal human experience and did not require a medical diagnosis. The newest edition of the DSM, the DSM-V removes this caveat, meaning that grieving people now fulfil the criteria for depression, which some have argued is an example of overmedicalisation or even pharmaceuticalisation (Abraham 2010; APA 2013).

As discussed in Chapter 5, the very definition of depression, including its conception as an illness, has been influenced by the pharmaceutical industry. One psychiatrist I interviewed reflected in-depth on the nature of depression and how it is treated:

There's a perception that there is this disease, if you like, called depression. And these drugs are anti-it. And I think there's a lack of education amongst prescribers. You know, it's the complexity and subtlety of mood disorders. People just see depression and think "oh, I'll give them an antidepressant and they'll get better" without realising its substantially more complex than that (Fieldwork Interview, Psychiatrist 3).

When I pressed the psychiatrist on where this view came from, they sighed and noted:

You know, I'm tempted to say from pharma, and I'm not sure it's entirely that ... we don't really have a good understanding of the underlying epidemiology and what the hell is actually going on in somebody's brain that makes them feel like that (Fieldwork Interview, Psychiatrist 3).

In the absence of a clear understanding of depression, its causes and its mechanisms, pharmaceutical companies have pushed their own models. The chemical imbalance theory is a popular model still used by the pharmaceutical industry. It suggests that depression is due to an imbalance of chemicals in the brain, and idea which has gained traction to the point that it is referred to by popular 'woke' social media celebrities (Dunn and Raskin 2018). However, despite the simplicity and attractiveness of this model, there is no empirical evidence supporting it (Healy 2004). I interviewed both GPs and psychiatrists who referred to chemical imbalance in their discussion of depression and its treatments.

With depression, there are three things we look into. Three aspects, we call it the biopsychosocial model. So, bio means medications, the chemical imbalance in your brain and how you can replace that with serotonin or another medication (Fieldwork Interview, Psychiatrist 4).

I don't know how they [antidepressants] work. I say to patients they're like the oil in a car, they give your brain a richer mixture to run on, and help it get up and running again after it's stalled. And they say "yeah, yeah, that's fair enough". It's an analogy I use and it bears some relationship to what we think is going on, but it's just a story that I give people that I like, and if it helps then good (Fieldwork Interview, Psychiatrist 3).

GPs and psychiatrists also mentioned using questionnaires, such as the Patient Health Questionnaire 9 (PHQ-9), which they use to aid their diagnosis. Whilst questionnaires like these have been commonplace in practice for many years now, the PHQ-9 was, in fact, originally developed with funds from the antidepressant manufacturer, Pfizer (Kroenke et al. 2001).

I grade the severity of their symptoms either with an official scale, such as the PHQ or the GAD score, and actually giving them a number... ...you can tell patients, "well, when you first came in your score was 17", three months down the line they might not feel better but if you read them the score and they've got a score of 10, then you can tell them "actually, your score has gone down" (Fieldwork Interview, GP 5). Healthcare professionals are increasingly finding themselves part of a system which frowns upon, or outright forbids, interacting with PSRs. Meanwhile, higher up the chain of command interaction with industry is encouraged:

The government for some time now has been very much trying to encourage more and more work with industry. They see industry financially supporting the NHS as an important strand to try and shore up the creaking finances, and yet that is completely the opposite view of many of the people working within the NHS and involved in many of the services. Particularly, I think this is the case in mental health (Fieldwork Interview, Psychiatrist 9).

Even if a healthcare professional chooses not to see a PSR or attend industry funded training events and conferences and has no physical interaction with the pharmaceutical industry whatsoever, it is impossible for their diagnostic and prescriptive decisions not to be affected by the pharmaceutical industry.

With tight budget cuts across everything, unfortunately we have to rely on funds from pharma companies to carry on attending conferences and to do CPD, to keep training. So, I think it's better to be aware of what's going on, rather than living in an ideal world where you believe you are not being influenced by pharmaceutical companies at all, which is not true (Fieldwork Interview, Psychiatrist 7).

Although there have been efforts to improve the ethics of healthcare professionals' interactions with pharmaceutical companies, such changes are undermined by a lack of resources and inconsistent messaging. With training budgets being consistently cut, pharmaceutical industry funded education becomes an increasingly attractive option, and for some healthcare professionals, the only option.

8.5 Conclusion

There is a knowledge vacuum in the depression disease area. We do not know what causes it, or how it operates, and so the pharmaceutical industry steps in to provide definitions and potential disease mechanisms. As NHS training budgets are cut, a vacuum in the continuing medical education of healthcare professionals also opens up. Nature abhors a vacuum, and wherever one exists in the broad realm of mental healthcare, pharmaceutical companies will step in. Although they fill it in a way which is useful to some extent, they also serve companies quests for profit. The conflict of interest and subtle biases that result from pharmaceutical companies occupying these spaces are real and highly problematic. However, without a sufficiently funded mental

healthcare system with independent information and continuing medical education for healthcare professionals, industry provided substitutes are the best we have.

Regulation has been successful in improving the ethical status of healthcare professional/industry collaborations, reducing the impact of the conflict of interest in some instances. Even informants who spoke frankly about being flown to exotic islands and who now lament being resigned to cheap hotels, acknowledge that such changes have been necessary for reducing the conflict of interest associated with interacting with pharmaceutical companies. However, the only way to completely eradicate the conflict of interest is to independently fund the education of healthcare professionals, the information resources they use, and the clinical trials which provide the evidence-base for drugs. This is an expensive ask and doing so would either potentially reduce the quality of expert-advice available to antidepressant manufacturers, or cause manufacturers to take their business to countries other than the UK. Whether it is what we ultimately want as a society remains open for discussion.

9. Raising Depression Awareness

9.1 Introduction

In the previous chapter, I considered the ways in which, via covert pharma money, pharmaceutical companies interact with (and market to) healthcare professionals. Moreover, the chapter examined the role of healthcare professionals in the antidepressant marketing process as gatekeepers to prescribing drugs and later as locksmiths. The gatekeeper status of healthcare professionals is further reinforced by the fact that advertising prescription drugs such as antidepressants to the public is illegal in the UK. Pharma money, here, operates to ensure that drugs continue to be used as cures for various disorders, including depression. However, pharma money is also used to influence the public or potential users – or, perhaps, that should be consumers - of antidepressants. It is here that awareness campaigns and charities are crucial.

Although antidepressant manufacturers cannot promote their products directly to the end-user, they are able to promote the symptoms of depression via disease awareness campaigns. This chapter therefore focuses on big money from Big Pharma-funded depression awareness campaigns, examining the impact that such funding can have on a campaign. It appears that the rationale for these campaigns, and the pharma money behind them, is to convince the public that they are depressed, and, moreover, that they should not feel ashamed for being depressed. Further to this, I explore the potential motives behind what often appear to be charitable donations.

In 2014, the 'Ice Bucket Challenge' went viral. Celebrities including Barak Obama, Charlie Sheen and Lady Gaga poured iced-water over their heads along with over 2 million members of the public. The purpose of the challenge was to raise awareness for amyotrophic lateral sclerosis (ALS). Known as motor neurone disease in the UK, ALS is an incurable, progressive condition with an average life expectancy of 2-5 years after diagnosis. The challenge became one of the most recognisable disease awareness campaigns in history. In the case of the Ice Bucket Challenge, awareness was being raised to promote donations to ALS charities to help patients and, ultimately, find a cure.

Disease awareness campaigns are diverse in terms of both their format and missions. They can be as pedestrian as the posters in GP waiting rooms that remind patients of the dangers of smoking-related illnesses. They might include coloured ribbons, YouTube videos encouraging viewers to get tested for gluten intolerance, or a leaflet on the correct way to self-examine for breast lumps. They can also include materials targeted at healthcare professionals, employers or politicians. What unites them is that they are media events which attempt to increase knowledge of a condition.

For pharmaceutical companies, disease awareness campaigns present an expedient opportunity. Whilst it is illegal to advertise prescription medications to the public, it is entirely legal for companies to fund disease awareness activities. Researchers such as Lexchin et al. (2003) and Lundh et al. (2015) found that, when research is funded by a pharmaceutical company, the findings of that research are more likely to be favourable to the interests of that company. Moreover, Wazana (2000) found that healthcare professionals who receive gifts from, or attend events funded by pharmaceutical companies have more expensive prescribing patterns. The phrase 'there's no such thing as a free lunch' is often used in association with the pharmaceutical industry, and, indeed, many researchers agree that pharmaceutical funding is not without its strings.

Over the course of Chapter 5, a pattern emerged. Throughout history, symptoms of low mood have been defined by those providing treatments. Following this narrative, in contemporary societies our understanding of depression is shaped and informed by private pharmaceutical corporations. We are sold the idea that depression is a chemical imbalance which requires a chemical solution. Disease awareness campaigns are integral to forming and changing public understanding of such conditions. Documents from pharmaceutical industry funded depression awareness campaigns thus have the potential to yield insights into how antidepressant manufacturers influence societal views on depression.

Pharmaceutical companies have a vested interest in their drug being prescribed, in addition to the rates at which a condition is diagnosed. Therefore, if a campaign

receives money from a pharmaceutical company it could, albeit unintentionally, promote a specific treatment option to its members or the public. Furthermore, they may contribute to the over-diagnoses of conditions via overmedicalisation or pharmaceuticalisation. Disease mongering refers to how pharma-funded charities can contribute to the over-diagnosis of conditions by overemphasising the prevalence of a condition, as well as medicalising vague symptoms which even 'normal' healthy people may be able to relate to (Moynihan and Henry 2006).

Since blockbuster SSRIs reached the UK market, depression awareness campaigns in the UK have consistently received funding from antidepressant manufacturers. This chapter explores each instance uncovered through the data collection process of pharmaceutical industry involvement in depression awareness campaigns. Beginning with the first UK depression awareness campaign, The Defeat Depression Campaign (DDC) in 1991 and concluding with The Work in Progress Campaign (WiPC) in 2016, this chapter examines how antidepressant manufacturers have used disease awareness campaigns as part of their wider marketing efforts. As identified in previous chapters, the context within which antidepressant manufacturers operate has changed vastly over the past quarter of a century. The impact such changes have had on the involvement of pharmaceutical companies in awareness campaigns is therefore discussed in detail.

This chapter is organised into three sections which highlight changes in the motivations of antidepressant manufacturers, from disease mongering to political pandering. I draw upon Peter Conrad's work on 'the shifting engines of medicalization' (2005) to argue that medicalisation continues to be driven to some extent by the profit motives of pharmaceutical companies. However, the way in which this 'engine' is expressed has changed. Ultimately, this chapter concludes that, whilst, historically, pharmaceutical companies have funded depression awareness campaigns to increase demand for their products, the motivations behind drug company investment in charities has changed in recent years. Rather than operating as a strategy to reach public audiences, antidepressant manufacturers now utilise these campaigns to satisfy the approval requirements of public and professional bodies, such as the British National Formulary (BNF) and NICE. Charities are imbued with multiple moralities,

which result in political and rhetorical power and engender trust (Loseke 1997) – a scarce resource for antidepressant manufacturers post Seroxat Scandal.

9.2 Becoming Aware: The Defeat Depression Campaign

A seminal moment in the understanding of depression and its pharmaceutical treatments in the UK was the DDC. Originally conceived of in September 1990 and running publicly from 1992 to 1996, the campaign was a collaboration between The RCPsych and The RCGP.

The DDC was the first disease awareness campaign launched in the UK focusing solely on depression. Although it was the first depression awareness campaign in the UK, it was inspired by similar movements which had launched elsewhere, the earliest example of which was run on the Swedish Island of Gotland. Aimed at training GPs on depression treatment and diagnosis, the Gotland campaign was openly funded by Ciba-Geigy Pharmaceuticals (Rutz et al. 1989a; Rutz et al. 1989b). A study conducted throughout the Gotland campaign found that the campaign's efforts to educate GPs on the diagnosis and treatment of depression resulted in increased competency amongst health professionals, which, in turn, translated into fewer psychiatric referrals and a lower suicide rate (Rutz et al. 1989a; Rutz et al. 1989b). The DDC was also influenced by the US campaign Depression Awareness Recognition and Treatment (D/ART), which was funded by American Prozac manufacturer, Eli Lilly. The DDC was also funded in part by Eli Lilly, although this was not always made apparent. Healy notes that one of the purposes of these campaigns was to 'shame' doctors into diagnosing depression by convincing them they were underdiagnosing the condition (Healy 2004, p. 10).

The DDC had several aims which developed over the course of its conception. The original proposal for the campaign, submitted in 1990, outlined 'a national campaign designed to assist general practitioners and other health care professionals in the recognition and treatment of depressive illness and to increase public awareness of the extent and treatability of depression' (RCPsych 1990, p. 8). The proposal also explicitly stated throughout that it was concerned specifically with 'Depression as a clinical illness' (1990, p. 4). This distinction is an important one when considering the

campaign in relation to concepts like disease mongering and medicalisation, as it suggests that The RCPsych were not interested in increasing awareness about or treating a broader understanding of depression, which would include a degree of normal human experience. The proposal also made the argument that depression is underdiagnosed by GPs due to a lack of training, and a reluctance on the behalf of patients to discuss symptoms due to stigma (1990, p. 5-6).

After the campaign concluded in 1996, several articles were published assessing the impact of the campaign (Donoghue et al. 1996; Orrell et al. 1996; Rix et al. 1999). Although prescribing both increased (Paykel 2001) and some argued improved (Donoghue et al. 1996) over the duration of the campaign, the campaign was less successful in its controversial aim to change the widespread public belief that antidepressants are not addictive (Paykel 2001).

One major criticism of the campaign is that it was funded by the pharmaceutical industry. Funding is a key issue when discussing the motives of a disease awareness campaign, as pharmaceutical funding of disease awareness campaigns can result in disease mongering (Moynihan and Henry 2006). In 2004, The RCPsych admitted to receiving £129,530 from pharmaceutical companies, however this chapter makes the case that this disclosed figure could be lower than the actual amount received.

Retrospectively, both Healy (Healy 2004) and (Moncrieff et al. 2005, p. 84) identify that the pharmaceutical industry played a role in the campaign, however neither reference how they came to know this information. Moncrieff et al. (2005) specify that the campaign received less than thirty per cent of its funds from the pharmaceutical industry, and whilst they do not provide the source of their information, it is likely they are referring to a figure noted in the minutes of a series of meetings on the influence of the pharmaceutical industry published by the House of Commons Health Committee (Committee 2004). In the minutes, Dr Kendall of The RCPsych claims that he believes that the DDC did not receive any funding from the pharmaceutical industry (Committee 2004, p. 131). However, Kendall's claim was queried and subsequently a copy of a letter from the RCPsych's president was presented stating that 'the campaign's total

income amounted to £449,800, of which only £129,530, that is 28.8 percent, came from pharmaceutical companies' (Committee 2004, p. 132).

A useful tactic adopted by investigative journalists, and recommended by the ICIJ, is to unearth previously forgotten or unavailable public documents. This informed my own research methodology, as I used the document archives of The RCGP and The RCPsych. Here, I gathered archival documentary evidence to corroborate the claims of both Healy (2004) and Moncrieff et al. (2005) that the campaign was funded, in part, by the pharmaceutical industry. The documents suggested that the original concept for the campaign was conceived of by The RCPsych, whilst funding was sought afterwards directly from pharmaceutical companies. This is exemplified in the following extracts:¹

Funding will be primarily from pharmaceutical companies and will be channelled to The RCPsych who will take the lead with input from our RCGP representatives (Trent to Payne, 1992)

The campaign itself is to be funded from a wide appeal directed mainly to the pharmaceutical industry and which will be endorsed by HRM the Prince of Wales as President of The RCPsych. According to Paul Freeling, funding has already been generously forthcoming but it is not clear how far these funds will go towards the depression campaign itself or towards the more general appeal which The RCPsych is also launching this year under the Presidency of HRH (Michaels to Long, 1991)

Perhaps most interestingly, in a letter to Long (1991) Butler notes that 'the campaign activity seemed to be coming together quite well in preparation for the launch on Thursday 5th December. Funding of £175,000 has been obtained for the planned attitude survey from a drug company'. This figure of £175,000 is larger than the £129,530 figure cited by the president of The RCPsych as representing the total income from pharmaceutical companies for the campaign, whereas Butler's letter suggests that this figure was donated by a single pharmaceutical company. Of course, these figures could differ for several reasons; perhaps the president's figure does not include funds for preparatory activities which took place before the campaign. It is also possible that the funds Butler mentioned were later withdrawn; however, based on the

¹ Names have been changed for the purposes of anonymity. The original letters are available at The RCGP archive in London. Please contact me for extra information to locate these specific sources.

published results of the survey, it is clear that the survey was ultimately funded by a pharmaceutical company.

Healy (2004) named Eli Lilly as the pharmaceutical company involved in the campaign, and multiple documents from the archives of both The RCGP and The RCPsych support this claim (RCPsych 1992,1993a; Orrell et al. 1996). Eli Lilly were, and still are, the manufacturers of Prozac; therefore, it would have been realistically within Eli Lilly's business interests to support a campaign which could lead to greater diagnosis and treatment of depression, thus growing the market for antidepressants. Although Eli Lilly were the company most directly linked to funding the campaign, they were not the only pharmaceutical company who contributed funds to the campaign. A fun run, organised as part of the campaign in 1995, aimed to raise funds and & awareness of depression, was backed by Seroxat manufacturer, Smith, Kline & Beecham (SKB). In correspondence to the Psychiatric Bulletin, Crown (1995) describes how the event 'had been well publicised and was generously sponsored by SKB'. Furthermore, an advert for the fun run appearing in the Psychiatric Bulletin acknowledged that the entry fee would be matched by SKB. In his correspondence, Crown (1995) noted that there were 250 runners, suggesting a donation from SKB of at least £750.

As aforesaid, one of the principal aims of the campaign was to change the public perception that antidepressants were addictive. This aim was established after a public attitudes survey identified that the public held this belief, which they claimed to be false. The public attitudes survey was carried out by the market research company Market & Opinion Research International (MORI), hence why this survey is often referred to as the MORI survey (Vize and Priest 1993). Whilst the research paper publishing the results of the MORI survey described the paper as 'Royal Colleges Commissioned' but with no direct mention of funding (Vize and Priest 1993), an internal document obtained from the archive of The RCGP specifies that the survey was funded by £175,000 from a pharmaceutical company (Butler to Long, 1991). A second paper publishing the results noted that funding was provided by the 'Defeat Depression Fund' and states explicitly that there were no conflicts of interest to declare (Priest et al. 1996, p. 859). Although the objective of the research was 'To investigate

the attitudes of the general public towards depression', most of the 'key messages' highlighted related to antidepressants:

- Before beginning its five year task, the campaign sought opinions from 2003 members of the public
- Most of the sample (78%) thought that antidepressants were addictive, and only 16% thought that they should be given to depressed people
- Most patients treated with antidepressants in primary care abandon taking them prematurely; fear of dependence is one likely explanation
- Patients should be informed clearly when antidepressants are first prescribed that discontinuing treatment in due course will not be a problem (Priest et al. 1996, p. 858)

To combat the alleged misconception identified in the MORI survey, many campaign materials, such as leaflets and media appearances, reassured GPs and the public that antidepressants are not addictive (RCPsych 1993b,1996; Tylee et al. 1996; Crow 2017). However, this aspect of the campaign proved problematic. Sam Kent, a researcher unrelated to the campaign, wrote many letters to the Royal Colleges throughout the campaign. These letters were discovered at The RCGP archive. Kent specified that there are a number of different potential definitions of 'addictive', questioning the precise definition they were using, and asking exactly what evidence they had to come to this conclusion (e.g. Kent to Crow 1992a; 1992b; 1993). The following is an extract from one of Kent's letters:

The DDC used the media to publicise categorical assurance that antidepressive drug treatments were 'not addictive' and did not cause benzodiazepine-type rebound and withdrawal problems. I asked for the evidence on which the assurances were based (i.e. what scientific research has cleared all anti-depressive drug treatments of causing dependence, rebound and withdrawal problems?). This research evidence either (a) exists or (b) does not exist. If (a) applies, your assurances are valid: if (b) applies, they are not valid, and the most you are entitled to claim is that you do not know if the drugs cause dependence, rebound and withdrawal problems. We seem to be left with (b), as you have cited no scientific research that has cleared the drugs ... Anyone with a knowledge of the history of medicine (which The RCGP has) knows that all psychoactive substances are likely to cause dependence: that doctors have successfully assured people otherwise, and successfully been proved wrong, and large numbers of trusting patients have paid for their mistakes. These tragedies were easily avoidable. To avoid yet another repetition, one would expect The RCGP to tell the public: (i) these drugs are not tested for dependence before being given to the public, not systematically monitored for dependence afterwards, so we do not know to what extent they may cause dependence, and (ii) history (and what we know about the brain) suggests that they are almost certain to cause dependence to varying extents in some people (Kent to Crow 1992b).

Kent wrote letters to individuals from both Royal colleges throughout the duration of the campaign demanding answers to these questions, however no answer was ever given. Upon receiving one of Kent's letters, Crow, an individual involved in organising the campaign, forwarded it to a college in a memo saying simply: 'Help!!!'. Although Kent raised valid concerns (which years later were proved correct), the campaign continued to promote the message that antidepressants were not addictive. It appears that the organisers of the campaign were conceptualising addiction as the presence of drug seeking behaviour, however it is likely the public understanding of addiction also included symptoms such as dependence and withdrawal

The MORI survey that the depression awareness campaign drew upon was also subjected to methodological criticisms from medical anthropologists, Sushrut Jadhav and Roland Littlewood (1994). The pair argued that, through being over simplistic, the survey neglected to grasp the complexity of how illnesses are conceptualised. Furthermore, they stated that launching a 'glossy educational campaign' based on a 'restricted public opinion survey' was 'frankly disturbing' (Jadhav and Littlewood 1994, p. 572).

9.2.1 Campaign outcomes

Although, as mentioned earlier, the reassurance that antidepressants are not addictive became a key message of the campaign, its impact was limited. Paykel (2001) notes that the prevalence of the belief that antidepressants are not addictive changed only slightly over the course of the campaign. Prior to the campaign, this belief was held by 78 per cent of the population (Vize and Priest 1993, p. 574; Priest et al. 1996), it then stayed the same when measured in 1995, and dropped to 74 per cent in 1997 at the conclusion of the campaign (Paykel 2001).

Publicly held beliefs can be difficult to change, and why this widely-held belief did not change is almost impossible to decipher. It is possible that the disconnect between the public and professional definitions of addiction may have been partially responsible. As noted previously, addiction can be understood as a variety of conditions, including dependence, withdrawal, and rebound (Kent to Crow 1992a). However, it is clear from documentary sources that the Royal colleges conceptualised addiction only as drug seeking behaviour, as exemplified by Paykel's reasoning that 'there is no street market for antidepressants' (Crow to Kent 1992a).

The disparity between the common and technical understandings of addiction came to the public's attention in 2002, when Panorama began airing a series of documentaries on GSKs SSRI, Seroxat (Jofre 2002,2003,2004,2007). In the first documentary, the audience was introduced to 'Helen', a 22-year-old woman who noted 'I've wanted to come off it for quite a few years now but when I stopped taking it, I was so ill that I had to start taking it again and doctors kept telling me that it was impossible to be addicted to them' (Jofre 2002). It is therefore possible that, whilst campaign leaflets and media promoted the message that antidepressants are not addictive, some individuals taking antidepressants were experiencing symptoms they considered to be contrary to this message.

Although the public perception that antidepressants were addictive changed little over the course of the campaign, prescriptions for all classes of antidepressants rose (Paykel 2001). The greatest increase in prescription was evident in the newer, SSRI category of drugs, which increased from half a million in 1991, to 5.4 million in 1996. However, older, cheaper TCA drugs remained the most popular kind of antidepressant, with 9.1 million prescriptions (Paykel 2001). Paykel (2001) notes that 'the Campaign was careful not to endorse any particular class of antidepressants', a statement which was supported by earlier materials published by the campaign (Paykel and Priest 1992) but less evident in later campaign documents (Tylee et al. 1996). Paykel posits that, although the increase in prescriptions cannot be entirely attributed to the Campaign, the Campaign nevertheless did have some impact.

9.3 The Era of Added Benefits: Depression Alliance

Whilst the DDC was the first depression awareness campaign in the UK, it was far from the last. From the late-1990s onwards, Depression Awareness Week was coordinated by the charity DA. The word charity often brings to mind words such as altruism and selflessness, and, indeed, the mission of charities is to improve the world in some way. However, it is often easy to forget that charities are organisations. They do not operate to generate a profit, but they still require money to come in to go about their charitable business. The government funds charities to some extent. Hence, even if you pretend to be in a rush when walking past a charity fundraiser on the high street, if you pay taxes you are already giving some money to charities. The rest of a charity's funds ordinarily come in the form of donations. Some of these donations come from members of the public who may sponsor a friend in a fun run or drop 20p into a bucket in front of a supermarket, but some of these donations also come from private companies. With respect to depression charities, these donations sometimes come from pharmaceutical companies, which can lead to a conflict of interest. This is because charities may be (consciously or unconsciously) influenced by their funders and alter the messages of their campaigns, resulting in disease mongering or pharmaceuticalisation.

Because of the potential conflict of interest which emerges when a mental health charity receives money from a company which profits from the treatment of a mental health condition, some charities refuse these donations. For example, the UK's largest mental health charity Mind adopts a strong stance against the acceptance of funds from pharmaceutical companies or device companies due to this potential conflict of interest. On their website, they note that 'Mind will not accept donations from or hold shares in companies manufacturing pharmaceuticals, lest this should compromise our position on the uses of medication' (Mind 2017). However, this stance is not universal, and has especially not been the case throughout history.

Throughout the 2000s, depression awareness activities have been most closely associated with the charity DA. Charities such as DA can be regarded as moral entrepreneurs to use Howard Becker's (2008) term. Moral entrepreneurs seek to influence the adoption and maintenance of norms within a society or group. Labels are

integral to this process, and therefore campaigns which aim to label and identify conditions are perfect projects for moral entrepreneurs.

In 2005, 2007, 2008, 2015 and 2016, DA received funds from antidepressant manufacturers in relation to their Depression Awareness Week activities. DA and its relationships with pharmaceutical companies will therefore be examined. Figure 6 below presents a timeline of depression awareness campaigns' antidepressant marketing authorisations.





In her 1997 paper, Loseke examines the construction of the idea of charity throughout the 20th Century. Loseke (1997) found that charities are imbued with multiple moralities, such as the sacred morality of religion and the human morality of compassion. Loseke proceeds to argue that these multiple moralities give charities 'political and rhetorical power' (1997, p. 425). Whilst the incentives for using depression charities to disease monger have decreased in recent years, the political and rhetorical power of charities remains. By linking themselves to charities, pharmaceutical companies are thus able to bask in some of the glow of their perceived moral goodness. Furthermore, as moral entrepreneurs, charities benefit by receiving funds to further their mission to alter societal norms.

Prior to merging win Mind in August 2016, DA was the largest depression specific charity in the UK². The website Seroxat Secrets (2005; 2008) points to two occasions where the charity accepted pharmaceutical funding for its annual depression awareness week. The accusations of this blog led me to file a FoIA request with the charities commission to obtain the company accounts, which confirmed that the charity was indeed a recipient of pharmaceutical funding.

In 2004, DA admitted to receiving 80 per cent of their funds from pharmaceutical companies (Committee 2004, p. 146). Whilst they were receiving the majority of their funds from pharmaceutical companies, debates dominated the public sphere over whether antidepressants were addictive, and whether they were safe for children to use: The so-called Seroxat Scandal. Mind, a charity which refuses donations from pharmaceutical companies, spoke out about the scandal (Committee 2004). However, rather than criticising their funder GSK, DA turned their criticism towards Panorama (HCHC 2004, p. 147).

Whilst bloggers have criticised DA's extensive and ongoing relationship with the pharmaceutical industry (e.g. Fiddaman 2017; SeroxatSecrets 2017; Truthman30 2017), it has not yet been the subject of formal academic research. The remainder of this chapter is dedicated to presenting and analysing the information gathered on DAs collaborations with the pharma industry, which draws upon sources such as the charity's accounts, leaflets, media coverage, and an interview with a DA board member.

9.3.1 Early Period: 1999

The investigative approach adopted for this research was particularly useful for uncovering and corroborating information from the past, when there was far less

² When writing the first draft of this chapter in 2017, I had a sentence here commenting on how a quick Google search of DA demonstrated their controversial nature. The first page of results included references to their 'clumsy conflicts of interest'. However, this is no longer the case. In 2018, these results have been relegated to page 9...

transparency than there is today. The earliest instance of DAs collaboration with pharmaceutical companies that I was able to identify was in 1999. An interview with an informant from a medical PR company uncovered an instance where DA received funds from an unnamed pharmaceutical company. In 1999, DA was paid to issue a leaflet to its members highlighting the prevalence of sexual dysfunction as a side-effect of most antidepressants. The leaflet was commissioned by a pharmaceutical company who were promoting a new antidepressant which did not have sexual side-effects. The intention was that individuals would go to their doctors asking for an antidepressant which would not cause sexual side-effects. Although the PR informant did not disclose the name of the medication, based on my own investigation into what drugs were on patent at that time, the most likely candidate is, Mirtazapine, which does not have sexual side-effects, but does commonly cause increased appetite and weight-gain; hence, why is prescribed by vets as an appetite stimulant for cats and dogs.

9.3.2 'Pulling Together': 2005

For Depression Awareness Week (Or National Depression Week as it was referred to at the time) in 2005, Eli Lilly and Boehringer Ingelheim collaborated with DA on a survey and subsequent report called 'Pulling Together – Body & mind depression symptoms survey report' (Depression Alliance 2005) – see Figure 7. The cover page highlights the statistic that '85% of patients believe that their quality of life would be improved if their *aches and pains* could be effectively managed' (emphasis in the original document).

Interestingly, the report comes three and a half months after the launch of a new antidepressant which claims to treat the aches and pains associated with depression (Lilly 2005). Duloxetine (brand name Cymbalta) was launched as the only antidepressant which also treats psychosomatic pain. The drug was discovered by Eli Lilly and then subsequently developed and marketed in collaboration with German pharmaceutical company, Boehringer Ingelheim, both of whom funded 'Pulling Together' via an 'unrestricted educational grant' (Depression Alliance 2005, p. 9). Prior to the launch of Duloxetine, the link between psychosomatic pain and depression was unclear and had not been explored in a great amount of detail (Korff and Simon 1996). 'Pulling Together' notes that depressed people experience aches and pains at four

times the rate of people not diagnosed with depression (Depression Alliance 2005, p. 5). However, it is important to note that the relationship between pain and depression is complicated by several factors. For example, people with chronic illnesses (of which a symptom may be pain) are more likely to experience depression (Korff and Simon 1996). Therefore, statistics emphasising the increased rate of 'aches and pains' in people with depression compared to those without depression do not necessarily point to the pain being psychosomatic or caused by depression.

The rest of the report presents the findings of two surveys conducted in November 2004. The first of which comprised responses of 644 DA members who were contacted via the charity. The second was conducted by market research company, TNS Healthcare, who surveyed 205 general practitioners. The results of the first survey present a comparison of what symptoms are experienced by people with depression versus what they would talk to a doctor about. The largest disparity occurred in relation to the symptom of sexual dysfunction, which was experienced by 48 percent of the respondents but reported to doctors by only 14 percent of them. Irritability, lack of pleasure and anger were also poorly reported with only 50 percent or less of the respondents who experienced these symptoms discussing them with their doctors. However, the symptoms discussed in the most detail in the report are 'general aches and pains' which were experienced by 49 percent of respondents, 33 percent of whom discussed the symptom with their doctor.

Throughout the report, aches and pains are privileged above other symptoms, regardless of what the survey data appears to show. This is most evident on page 6 of the report which presents data from the GP survey – see Figure 7. The symptom reported to be least likely to be resolved by antidepressant treatment was fatigue, as reported by 62 percent of the respondents. However, attention is given instead to aches and pains which appears inexplicably in large faded text beneath a graph on remission.





The privileging of aches and pains in Figure 7 in a way which corresponded to the interests of the report's funders was noticed by the anonymous industry commentator and critic who writes the blog 'Seroxat Secrets' (2017). The author noted that the stated purpose of 'Pulling Together' (to show how people pull together to combat depression) was not evident at all in the report. The author was vocal about their criticisms of the campaign and continually reached out to the DA for comment and clarification. In 2007, they reported receiving the following response from DA CEO, Jim Thompson:

I apologise for not addressing your point about "Pulling Together" and have just spent time re-reading it (in fact, I'm not even sure if I was still with DA when it was published, but I may have been). I have also been reading your critique of it, which is conspiracy theory of the first water. I doubt I can convince you of this, but I can assure you that the research was undertaken for very different reasons than those you assume ... a piece of research was planned, to try to underline that somatic symptoms are (or can be) very much a part of the illness. That was the strategy – it had nothing to do with Cymbalta. You can take my word for that or not – it is immaterial to me because, whether or not it satisfies your concerns, it is the truth. If you want to take it further, then take the matter up with the ABPI – and before you counter that the ABPI is an industry body, I would remind you that they have suspended, I believe, at least three of their Big Pharma members in the past year, for the sort of activity you imply (Seroxat Secrets 2007).

The author of Seroxat Secrets noted that Thompson's response still failed to explain how the report links to 'Pulling Together'. Furthermore, my own analysis of the document suggests that, even if the initial strategy was 'nothing to do with Cymbalta', it is clear that 'Pulling Together' privileges information which supports the interests of its funders. This is most telling when a simple search function is executed on the document. The term 'aches and pains' appears twenty-two times in the eight-page document. Sexual dysfunction comparatively occurs seven times. The most common symptom of depression, low mood, occurs once. 'Pulling Together' can therefore be considered an example of pharmaceuticalisation, in that the boundaries of the diagnosis of depression are being expanded and blurred to suit the motives of the pharmaceutical industry.

9.3.3 'Now We're Talking!': 2006/7

In December 2006, in collaboration with mental health charity SANE and the pharmaceutical companies Eli Lilly and Boehringer Ingelheim, DA developed another campaign called: 'Now We're Talking!'. As with 'Pulling Together', 'Now We're Talking!' consisted of a survey sent to DA members – see Figure 8. Moreover, the survey was posted on SANEs website. The final report presents recommendations for the diagnosis, informed treatment, and ongoing management of depression. The report also formed the basis of Depression Awareness Week, 2007.

Figure 8: Now We're Talking

1. Initial recognition of symptoms and diagnosis

The *Now We're Talking!* survey showed that there are a wide range of long-term conditions commonly associated with depression. People with depression are likely to suffer from other health conditions such as high blood pressure (14 per cent), chronic painful conditions (12 per cent) and arthritis (11 per cent)¹⁰. However, the QOF is currently limited to recommending that GPs identify how many patients on their diabetes and coronary heart disease registers have been screened for depression. Although it would be difficult to look for depression in all associated conditions, there is scope to expand the QOF and encourage the identification of depression in other disease areas.

Depression Alliance and SANE recommend... the development of a QOF indicator that encourages GPs to:

- Look for depression in a wider range of disease areas, in addition to diabetes and coronary heart disease.
- Take into account the broad range of psychological and somatic symptoms associated with depression when considering an initial diagnosis.

As a GP you can... actively check for all symptoms associated with depression in patients presenting with other long-term conditions and consider their relevance when making your initial diagnosis.

As a patient you can... improve your awareness of the many and varied symptoms of depression and proactively highlight these to your GP to help them i) with their initial diagnosis or ii) identify relapse.

2. Informed choice of treatment

The *Now We're Talking!* survey showed that when it comes to depression, some patients currently feel their opinions on treatment are not adequately considered or discussed and they would welcome more ongoing advice and support from their GP¹⁰.

Depression Alliance and SANE recommend... the development of a QOF indicator that supports the increased involvement of patients in their treatment decisions.

As a GP you can... provide patients with additional information on alternative and/or available treatments with reference to the NICE stepped care model¹¹. If time does not allow, you can refer patients to an appropriate support group or third party patient organisation.

As a patient you can... make yourself aware of available treatments through your own research or through contact with a suitable support group or third party patient organisation. Having done this, you will be in a better position to ask your GP about the suitability of particular treatments for you.

3. Ongoing management

Over half of respondents (58 per cent) in the *Now We're Talking!* survey felt more ongoing support from GPs would lead to an improvement in care¹⁰. The results showed that over half of respondents (57 per cent) first started to experience depression over ten years ago¹⁰, yet a significant proportion of people who have had several episodes of depression or who suffer from chronic depression (39 and 48 per cent, respectively) reported not being advised how long to stay on treatment¹⁰. The fact that over half of survey participants treated with antidepressants (55 per cent) had at some point terminated their treatment early may reflect this lack of adequate guidance¹⁰.

Depression Alliance and SANE recommend... the development of a QOF indicator that supports GPs in the identification, management and ongoing care of those with depression.

As a GP you can... keep in regular contact with patients with a known history of depression and, if and when prescribing antidepressants, provide an 'information prescription' to inform patients about the medication and possible side-effects, and also provide support for treatment adherence.

As a patient you can... be vigilant for signs of relapse and seek regular treatment reviews with your GP.

(Depression Alliance, 2007)

The symptoms of aches and pains are mentioned four times across the sixteen-page document, a huge reduction compared to the twenty two citations in the eight-pages of 'Pulling Together'. Indeed, 'Now We're Talking!' is altogether more nuanced in its reflection of the aims of its funders. More varied phrasing is used to emphasise that depression has many symptoms, including physical symptoms, which both healthcare providers and patients need to be educated about.

9.3.4 'The Inside Story': 2008

In 2008, DA received funds from Servier, as well as the Medical PR company they hired, to release a report titled 'The Inside Story' (Depression Alliance 2008). Servier had released a new drug which operated in a different way to many existing drugs. Instead of working on neurotransmitters like serotonin, Servier's drug, Valdoxan, was similar in structure to melatonin, the hormone associated with sleep. It is for this reason that the drug is characterised as a melanotonic antidepressant, and one of the main symptoms of depression that it treats is the regulation of sleep. Sleep disturbances have long been considered to be a symptom of depression, with patients either reporting being unable to sleep or unable to stop sleeping. The inclusion of sleep disturbance as a symptom in DA's 2008 campaign is therefore not absurd. However, similarly to 2005, messages from the 2008 campaign appeared in national news media, including *The Guardian*, with no reference to Servier's funding (Gaines 2008).

The Guardian article and others appear to be based on a newswire press release that states that Servier's funding was used to conduct a survey referred to in a report called 'The Inside Story' (Press Association Mediapoint 2008). The first-half of the press release for the survey foregrounded the survey's investigation into the experiences and opinions of workers with depression. However, the second-half of the press release focuses on sleep-related questions, noting that 83% of the 288 survey respondents felt their work was negatively affected by poor sleep, whilst 40% reported that they had lost their job because of poor sleep.

Indeed, the only quote in the press release is from DA Chief Executive, Emer O'Neil, who notes: 'Sleep disturbance can have a major impact in people with depression, and this data also highlights the importance of healthcare professionals and patients

working in partnership to manage their depression in a way that will not negatively impact on their sleep.' (Press Association Mediapoint 2008).

O'Neil's acknowledgement, here, that sleep is an important issue in depression is supported by numerous peer-reviewed studies (Tsuno et al. 2005). O'Neil's second point appears to be the most telling with respect to the DAs funding. The most commonly used class of antidepressants, SSRIs, can have the side-effect of causing insomnia in some patients. O'Neil's argument that depression should be managed in a such way that does not negatively affect sleep thus appears to be directed specifically at SSRIs. Both depression itself and SSRIs are associated with sleep disturbances, but yet the survey does not appear to differentiate between the two. It is therefore interesting that O'Neil's conclusion is that depression should be managed in a way not to negatively affect sleep, rather than, say, in a way that improves sleep. One reason as to why she may use the double negative when focusing on sleep disturbance as a side-effect of other treatments, is that there are multiple treatments that do not cause sleep disturbance. Notably, sleep disturbance is not a side-effect of talking treatments. Servier's drug, Agomelatine, is the only antidepressant that regulates sleep. Therefore, had O'Neil recommended that depression should be managed in such a way which improves sleep, then the press release would have been defined as 'promotional' by the ABPI, thus making Servier guilty of direct to consumer marketing.

Although O'Neil's statement avoids being promotional by the ABPIs standards, it is clear that her comments on how depression should be managed are influenced by DAs funders. The press release is therefore indicative of a conflict of interest, because, as a charity, DA are trusted and relied upon to give unbiased information on the management of depression. The ability to give clear unbiased information, in this case, is inhibited by the funding they received from Servier.

The impact of the conflict of interest evident in 'The Inside Story' is unclear. As mentioned previously, sleep disturbance is a widely-documented symptom of depression. Moreover, there is evidence to suggest that SSRIs cause insomnia in some individuals (Dording et al. 2002). The problems Servier were attempting to solve

with Agomelatine were thus not fabricated to market the drug. However, what is evident is that DAs statements regarding the management of depression were influenced by the funding, and, as such, the impartiality of the charity was undermined.

9.4 The Shifting Mediators of Medicalisation

In 2005, Peter Conrad published an article titled 'The Shifting Engines of Medicalization'. In the paper, he used case studies to examine the factors informing the expansion and contraction of medical diagnoses. Ultimately, he found that medicalisation had become increasingly driven by commercial and market factors, namely, pharmaceutical companies (Conrad 2005). In the past, medicalisation had been driven, in part, by healthcare professionals. However, Conrad found that, from the mid-1980s onwards, they had been relegated to a mediator role in the medicalisation process. Conrad's findings are reflected in disease awareness campaigns such as 'The Inside Story,' which surveyed healthcare professionals, who, as discussed in the previous chapter, were the target of marketing campaigns. In this section, I suggest that, having already experienced a shift in the engines of medicalisation, we are now witnessing a further shift in the mediators of medicalisation. Campaigns such as the DDC focused on the public as meditators of medicalisation, The Inside Story focused on GPs, whilst the 2015 and 2016 campaign 'Work in Progress' turned its attention to politicians. This shift correlates with a broader trend within the industry away from overt marketing towards a political agenda. As is discussed later in this chapter, disease mongering among the public is no longer profitable. Rather, the issue of whether a drug is approved, and whether it can be prescribed in a given geographical area, is an increasingly political one.

9.4.1 'Work in Progress': 2015/16

In April 2015, as part of Depression Awareness Week, DA launched the 'Work in Progress' (WIP) campaign. As was the case with previous campaigns, the funder of WIP had a new antidepressant which had recently been released to market. The funder was Lundbeck, and the new antidepressant was a drug with the chemical name, vortioxetine, which was being marketed under the brand name, Brintellix. Similar to agomelatine and duloxetine, vortioxetine has a key feature which

differentiates it from its competitors – it claims to improve cognitive function and decision-making in depressed individuals.

As with 'Pulling Together', 'Now We're Talking!' and 'The Inside Story', WIP consisted mainly of a report based on a survey. Rather than being a survey of DA members or healthcare professionals as was the case with past campaigns, the survey conducted for WIP was with members of parliament. Furthermore, unlike previous surveys commissioned by DA, the full survey data is publicly accessible online – see Figure 9. This transparency enabled me to see the specific questions posed to respondents. In doing so, I identified two questions (Q9 and Q11) out of 21 which reference specific symptoms of depression, including cognitive symptoms such as trouble concentration and indecisiveness, which vortioxetine aims to treat.

The other questions posted to the MPs mainly assessed respondents' understanding of depression and perception of stigma. The transparency of the survey, and the balance evident in the survey questions, are reassuring.
Figure 9: Work in Progress Survey

| | PARTY | | | COL | INTRY | REGION | | | DATE O | FBIRTH | MAF | GINALIT | Y | LENG | TH OF SE | GENDER | | | |
|--------------------------------------|-------|------|------|----------|-------------|------------------------|-------|--------------|--------|-------------|-------|--------------|----------------|------|-------------|---------------|-------|------|--------|
| | Total | Con | Lab | Other | Eng land | Wales/ Scot & NI | South | Mid lands | North | Pre 1960 | 1960+ | 0.1- 9.9% | 10.0- 19.9% | 20%+ | Pre 1997 | 1997- 2009 | 2010+ | Male | Female |
| Total | 50 | 24 | 22 | 4 | 38 | 12 | 18 | 12 | 20 | 27 | 23 | 18 | 12 | 20 | 3 | 20 | 27 | 44 | 6 |
| | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Loss of interest in daily activities | 47 | 23 | 20 | 4 | 37 | 10 | 16 | 12 | 19 | 25 | 22 | 16 | 12 | 19 | 2 | 20 | 25 | 42 | 5 |
| | 94% | 96% | 91% | 100% | 97% | 83% | 89% | 100% | 95% | 93% | 96% | 89% | 100% | 95% | 67% | 100% | 93% | 95% | 83% |
| Low mood or sadness | 45 | 21 | 20 | 4 | 35 | 10 | 17 | 11 | 17 | 24 | 21 | 16 | 11 | 18 | 2 | 19 | 24 | 40 | 5 |
| | 90% | 88% | 91% | 100% | 92% | 83% | 94% | 92% | 85% | 89% | 91% | 89% | 92% | 90% | 67% | 95% | 89% | 91% | 83% |
| Trouble concentrating | 40 | 18 | 20 | 2 | 29 | 11 | 12 | 10 | 18 | 23 | 17 | 12 | 11 | 17 | 3 | 15 | 22 | 36 | 4 |
| | 80% | 75% | 91% | 50% | 76% | 92% | 67% | 83% | 90% | 85% | 74% | 67% | 92% | 85% | 100% | 75% | 81% | 82% | 67% |
| Trouble sleeping/insomnia | 40 | 18 | 18 | 4 | 33 | 7 | 11 | 11 | 18 | 21 | 19 | 14 | 10 | 16 | 2 | 18 | 20 | 35 | 5 |
| | 80% | 75% | 82% | 100% | 87% | 58% | 61% | 92% | 90% | 78% | 83% | 78% | 83% | 80% | 67% | 90% | 74% | 80% | 83% |
| Crying for no reason | 37 | 18 | 17 | 2 | 27 | 10 | 12 | 11 | 14 | 22 | 15 | 10 | 9 | 18 | 1 | 17 | 19 | 33 | 4 |
| | 74% | 75% | 77% | 50% | 71% | 83% | 67% | 92% | 70% | 81% | 65% | 56% | 75% | 90% | 33% | 85% | 70% | 75% | 67% |
| Indecisiveness | 29 | 11 | 15 | 3 | 19 | 10 | 10 | 6 | 13 | 21 | 8 | 11 | 8 | 10 | 2 | 13 | 14 | 26 | 3 |
| | 58% | 46% | 68% | 75% | 50% | 83% | 56% | 50% | 65% | 78% | 35% | 61% | 67% | 50% | 67% | 65% | 52% | 59% | 50% |
| Aggressive behaviour | 25 | 12 | 12 | 1 | 20 | 5 | 8 | 7 | 10 | 15 | 10 | 8 | 6 | 11 | 1 | 10 | 14 | 23 | 2 |
| | 50% | 50% | 55% | 25% | 53% | 42% | 44% | 58% | 50% | 56% | 43% | 44% | 50% | 55% | 33% | 50% | 52% | 52% | 33% |
| Forgetfulness | 21 | 9 | 11 | 1 | 16 | 5 | 7 | 5 | 9 | 12 | 9 | 6 | 7 | 8 | 1 | 8 | 12 | 18 | 3 |
| | 42% | 38% | 50% | 25% | 42% | 42% | 39% | 42% | 45% | 44% | 39% | 33% | 58% | 40% | 33% | 40% | 44% | 41% | 50% |
| None of these | | • | | | • | | • | | | | : | • | | : | - | | | - | - |
| Don't know | • | - | - | - | - | • | - | - | - | - | - | • | : | : | - | - | - | - | - |

Awareness of Depression among Parliamentarians - UK Q9. Which of the symptoms below, if any, do you associate with depression in general? Base: All respondents

Table 28/1

| | | PARTY | | | COUN | ITRY | REGION | | | DATE O | F BIRTH | MA | RGINALIT | Y | LENG | TH OF SE | GENDER | | |
|------------------------------|------------|------------|------------|-----------|-------------|------------------------|------------|--------------|------------|-------------|------------|--------------|----------------|------------|-------------|---------------|------------|------------|-----------|
| | Total | Con | Lab | Other | Eng land | Wales/ Scot & NI | South | Mid lands | North | Pre 1960 | 1960+ | 0.1- 9.9% | 10.0- 19.9% | 20%+ | Pre 1997 | 1997- 2009 | 2010+ | Male | Female |
| Total | 50 100% | 24 100% | 22 100% | 4 100% | 38 100% | 12 100% | 18 100% | 12 100% | 20 100% | 27 100% | 23 100% | 18 100% | 12 100% | 20 100% | 3 100% | 20 100% | 27 100% | 44 100% | 6 100% |
| Lack of motivation and drive | 38 76% | 21 88% | 14 64% | 3 75% | 31 82% | 7 58% | 14 78% | 11 92% | 13 65% | 21 78% | 17 74% | 12 67% | 12 100% | 14 70% | 3 100% | 15 75% | 20 74% | 34 77% | 4 67% |
| Stigma | 25 50% | 10 42% | 12 55% | 3 75% | 19 50% | 6 50% | 8 44% | 5 42% | 12 60% | 12 44% | 13 57% | 5 28% | 7 58% | 13 65% | - | 10 50% | 15 56% | 24 55% | 1 17% |
| Isolation | 20 40% | 9 38% | 9 41% | 2 50% | 14 37% | 6 50% | 7 39% | 2 17% | 11 55% | 7 26% | 13 57% | 9 50% | 4 33% | 7 35% | 1 33% | 6 30% | 13 48% | 19 43% | 1 17% |
| Lack of concentration | 17 34% | 10 42% | 7 32% | : | 13 34% | 4 33% | 5 28% | 8 67% | 4 20% | 11 41% | 6 26% | 5 28% | 6 50% | 6 30% | 3 100% | 7 35% | 7 26% | 14 32% | 3 50% |
| Sadness | 9 18% | 6 25% | 3 14% | : | 8 21% | 1 8% | 4 22% | 2 17% | 3 15% | 5 19% | 4 17% | 2 11% | 4 33% | 3 15% | : | 4 20% | 5 19% | 8 18% | 1 17% |
| Indecisiveness | 9 18% | 6 25% | 2 9% | 1 25% | 6 16% | 3 25% | 5 28% | 3 25% | 1 5% | 8 30% | 1 4% | 4 22% | 1 8% | 4 20% | 2 67% | 3 15% | 4 15% | 9 20% | - |
| Loneliness | 9 18% | 4 17% | 4 18% | 1 25% | 8 21% | 1 8% | 4 22% | 1 8% | 4 20% | 5 19% | 4 17% | 5 28% | 1 8% | 3 15% | - | 3 15% | 6 22% | 7 16% | 2 33% |
| Other | 3 6% | : | 2 9% | 1 25% | 2 5% | 1 8% | 1 6% | - | 2 10% | 2 7% | 1 4% | 1 6% | - | 2 10% | - | 3 15% | - | 3 7% | - |
| None of these | 1 2% | - | 1 5% | - | - | 1 8% | 1 6% | - | - | 1 4% | : | 1 6% | - | - | - | 1 5% | - | 1 2% | - |
| Don't know | 1 2% | : | 1 5% | : | 1 3% | : | : | : | 1 5% | : | 1 4% | : | : | 1 5% | - | : | 1 4% | · . | 1 17% |

Awareness of Depression among Parliamentarians - UK Q11. What, in your view, are the biggest barriers to someone with depression gaining and retaining employment? Base: All respondents

Table 21/1

The 32 page WIP report draws upon a number of sources in addition to the MP survey data, with the proposed aim of 'Improving employment outcomes for people with depression' (Depression Alliance 2017, p. 0). The report contains three instances in which cognitive symptoms are discussed; the following excerpt from page nine, in Figure 10, includes two, whilst the other is on page 12.

Figure 10: Work in Progress

Symptoms of depression as a barrier to retaining employment

Depression tends to be categorised as 'mild', 'moderate' or 'severe' depending on the intensity of symptoms present. However, these distinctions are redundant and, in reality, based almost solely on diagnosis rather than functional impairment. So-called 'mild' disorders can produce adverse occupational outcomes.²⁷

Every depressive episode is different and unique to the individual. The experience of depression, and the consequences it might have for employment, are entirely personal and may be experienced very differently by different people, despite having the same diagnosis.

The symptoms of depression can be split into three main categories. Various examples are included in Fig.1 but do not represent a list of all the symptoms that are associated with depression: The symptoms of depression can cause difficulties in all aspects of daily life, including employment. The <u>cognitive</u> symptoms of depression – concentration difficulties, indecisiveness, forgetfullness, slow thinking speed, difficulty problem solving, difficulty planning – are present up to 94 percent of the time during an episode of depression.²⁸

Therefore, for many, coping with depression while holding down a job can be hard. For example, at work, depression can affect an employee's ability to make decisions, get started on tasks, keep an accurate work diary, remember to attend meetings, recall the details of conversations or requests, find the words to enable them to communicate their ideas effectively, plan their working day, work accurately, concentrate on tasks, complete work on time, understand complex matters, control their emotions and maintain good working relationships.

Fig. 1



Cognitive dysfunction had long been understood as a symptom of depression prior to both WIP and Lundbeck's development of vortioxetine (e.g. Vasic et al. 2008). This point was emphasised by a researcher I interviewed, who had been researching the link long before being approached by Lundbeck to assist with measuring cognition in clinical trials.

There's a very rich literature on that (cognitive dysfunction in people with a diagnosis of depression) and I've contributed to that in the past ... that's why I get hired by companies (Fieldwork Interview, Neuroscientist 1).

The inclusion of cognitive symptoms of depression in the MP survey and the WIP report are therefore not necessarily indications of bias, albeit their inclusion is certainly in keeping with the interests of Lundbeck.

Overall, then, WIP represents an ethical progression in the collaboration between DA and pharmaceutical companies. When compared with 'Pulling Together', there is a vast reduction in the instances of what could be interpreted as covert marketing messages. In the following section, I attempt to explain why.

9.4.2 Same engine, different paintwork

A clear change is evident when comparing earlier Depression Awareness Weeks and the DDC with the latest Depression Awareness Week. In earlier campaigns funded by pharmaceutical companies, we see echoes of marketing messages (Depression Alliance 2005,2008) and an over-emphasis on symptoms However, the Depression Awareness Weeks funded by Lundbeck do not over-emphasise the depressive symptoms that Lundbeck's latest drug uniquely treats. This change begs the question: if companies are no longer funding disease awareness campaigns to subtly promote the features of their new drug, then why are they funding them? Conrad (2005) found that the pharmaceutical companies' profit motive was a key engine of medicalisation, in that corporations are obliged to make money for their shareholders. This prioritisation of profit above all else is what leads Bakan (2012) to argue that corporations are psychopaths. So, why would a psychopath donate to charity? The critical argument in extant literature is that Lundbeck would fund an awareness campaign to increase awareness of depression, because it makes more people think they have it, which, in turn, grows the pool of potential patients via disease mongering (Moynihan and Henry 2006). However, whilst this might have been a useful tactic in the 1990s, it is unlikely that disease mongering in 2016 would benefit Lundbeck in the same way. Firstly, awareness of depression is already high, and the recent campaigns funded by Lundbeck do not contain evidence of attempting to widen the definition of depression by focusing on lesser-known symptoms.

Secondly, Lundbeck's new drug is a second-line antidepressant, meaning it would only be used with those patients who have already tried at least two (cheaper) antidepressants without experiencing improvement. Therefore, if Lundbeck were attempting to widen the definition of depression to include 'healthy' individuals, then it is unlikely these new patients would progress straight to a second-line antidepressant. Furthermore, as emphasised by several pharmaceutical representatives, companies no longer want their new drugs prescribed in healthy populations as it erodes trust and provides healthcare professionals and patients with a bad experience, which, in turn, leaves the company vulnerable to scandal and harms their profitability. As one respondent observed:

Obviously, every company is not a charity, every company has to generate profits to their shareholders, and, more importantly, have the funds to continue investment into research and development, bring the drugs to market, and that's a massive cost. So, absolutely, companies are driven by generating profit. But, because we are such a regulated industry, the main thing is that medicines are used in the right patients. So, a lot of the conversations over the years I've spent having are, whether it be policy makers, budget holders or clinicians, etc., are, you need to get this medication right in the right patients, because the last thing you want is it being used over here in the wrong group of patients. Particularly, say, in mental health, because the patient is going to have a bad experience, the clinician is going to have a bad experience, and then, potentially, everyone's going to say "oh, that medicine doesn't work", but they're not going to know that it didn't work because it was used in the wrong patient (Fieldwork Interview, PSR).

Whilst companies appear to have moved beyond actively promoting antidepressants

in healthy populations, antidepressant prescriptions continue to rise. This is possibly due to societal changes such as reduction of stigma, and the persistence of the chemical imbalance theory which will be discussed in more detail in chapter 11.

Beyond the straightforward disease mongering of early campaigns, my interviews with pharmaceutical representatives, PR professionals and pharmacists uncovered wholly different reasons for industry investment in charitable organisations: to influence policy and regulators.

In the UK, before new drugs are made available to the public they go through an approval process, during which the manufacturers must demonstrate that the drug is safe and effective. In addition to this, to make it on to formularies the drug must demonstrate good value for money. As discussed in the history section of this thesis, Malerba and Orsenigo (2015) argue that the pharmaceutical industry has now entered into the era of 'the winter of discontent'. Today, drugs must compete against an ever-growing selection of drugs. If the Olympics operated like the drug market, then every four years 100m sprinters would be racing against every other former Olympic champion who would not have aged a single day. In such a climate, winning becomes increasingly difficult. The pharmaceutical industry's response to this scenario can be likened to increasing the number of medals and increasing the prize money to be shared amongst the winners. One way through which they do this is by emphasising the 'disease burden'.

Disease burden is defined as the impact of the condition, which is ordinarily understood in terms of mortality, financial cost and the propensity to disable (Lopez et al. 2006). Manufacturers use disease burden in applications for marketing approval, and in discussions with medicine management committees who decide what drugs are included on a formulary. If companies can demonstrate that the condition their drug treats has large costs, particularly financial costs which politicians are most sensitive to, then they are better able to make the case for their new drug which is likely more expensive than existing treatments. For this reason, in some marketing materials for, Brintellix, Lundbeck focus on the financial costs of cognitive dysfunction in depression, particularly how these symptoms impact upon the work performance of depressed individuals. Presently, Brintellix is the only antidepressant which treats cognitive dysfunction. Hence, whilst the drug is more expensive than generic SSRIs and off-patent third-line treatments, Brintellix may work out cheaper for society overall due to the money saved in sick days, mistakes, poor decision-making and so on.

Disease burden is not only an area in which the interests of pharmaceutical companies and charities align, but, rather, it is an area which also aligns with the interests of politicians. If DA were to say 'Depression is a very mild condition which barely impacts the lives of people who have it', then they would be undermining the premise for the very existence of their charity and the jobs of the people who work there. Charities thus have a vested interest in communicating about the impact a condition has on the lives of its sufferers. Furthermore, individuals who work for such charities often have personal experience of the condition and may even have experienced stigma due to a lack of societal understanding. Charities are advocates for conditions. It is for these reasons that charities organise disease awareness campaigns, whilst the overlap in interests between charities and companies make such campaigns ideal for collaboration and building relationships. Depression charities therefore have an interest in wanting depression to be taken seriously by politicians and regulators.

In addition to using quantitative data to communicate the magnitude of a condition and its costs, qualitative data is also used to demonstrate disease burden. Patient narratives are rich sources of information about the day-to-day experiences of someone living with a condition. Charities such as DA have access to numerous patients willing to talk about their experiences. An informant who worked in the field of medical PR explained the importance of charities gaining access to patient case studies.

Charities are very important in pharmaceutical communications. They allow the patients' voices to be heard illustrating the impact of the disease or condition, easing access to opinion leaders and patient case studies and in proving a credible and relevant third-party perspective on your story. Charities are also vital in calling for changes in policy and in supporting the case for access to medicines, whether that means drug approval or budget allocation (Fieldwork Interview, Medical PR Professional 5). To be approved and make it onto formularies, manufacturers must make the case that their drug provides value for money. Charities therefore add legitimacy to the condition and its treatments and, as highlighted in the above extract, provide access to patient case studies that illustrate the impact of a disease on a personal level. PR informants noted that, rather than being used as distributors to promote marketing messages to potential patients, *charities are now valued for their reputation*. Charities are not benign entities, rather, as Loseke (1997) suggests, they have political and rhetorical power. In the wake of the Seroxat Scandal and others like it, pharmaceutical companies strive to retain and, where possible, improve their reputation. However, public trust has been depleted by these scandals. Due to their power and perceived moral virtue, charities are imbued with the very trust pharmaceutical companies lack. This, along with their overlapping interests in demonstrating disease burden, makes charities desirable partners for pharmaceutical companies.

I think some patient groups really are patient groups and they start off with the best of intentions, and perhaps they get infiltrated or they change over time. And others are complete total examples of astroturfing. They're set up by the drug companies to create credibility, to commission the research by the same drug company that ties in with the marketing (Fieldwork Interview, Industry Commentator 1).

Due to their personal and financial connections to charities, interests can overlap with the interests of pharmaceutical companies. It is in these instances that charities can use their political and rhetorical power (Loseke 1997) to influence decision-makers. WIP is an example of the political power of charities in action. The campaign stood out from its predecessors due to methodological differences in the survey which informed the campaign. Rather than polling patients or GPs, the survey focused on MP's. The results of the survey highlighted gaps in the knowledge and understanding of MPs, along with emphasising how important MPs perceive mental healthcare to be. The survey demonstrates a change in focus from patients towards policy, a change which is in keeping with the profit motives of pharmaceutical companies. Therefore, these interactions are still motivated by profit. The 'engine', as Conrad (2005) puts it, is therefore unchanged. However, because of societal changes, partaking in overt disease mongering aimed at potential patients is simply no longer profitable. Consequently, there has been a shift in the targets of these campaigns from the public to politicians. This change of focus in industry-charity relations within the depression

sector from the public to regulators has yet to be explored in the literature, and, as such, offers a rich area for future enquiry.

9.5 Conclusion

Historically, pharmaceutical companies have used charities, particularly disease awareness campaigns, to fund a covert marketing message: that depression exists and that pills manufactured by Big Pharma corporations offer a cure. Such campaigns exemplify Conrad's (2005) argument that pharmaceutical companies are the key driver of medicalisation. This was evident in the DDC where the potential to become dependent on antidepressants was downplayed (e.g. Priest et al. 1996), as well as in the 2005, 2007 and 2008 Depression Awareness Weeks. In each of these Depression Awareness weeks, a lesser-known symptom of depression was highlighted, which corresponded with the symptom that the funder's new drug uniquely treated. More recent collaborations between pharmaceutical companies and charities, however, show less evidence of this kind of subtle marketing. Most interestingly, the 2016 Depression Awareness Week document, which was produced via a collaboration of mental health charities and funded by Lundbeck, did not over-emphasise the depressive symptom that their drug uniquely treats: cognitive dysfunction.

This chapter has argued that, whilst there has been a positive move away from antidepressant manufacturers using charities to contribute to subtle disease mongering, pharmaceutical companies are incapable of behaving altruistically due to their commitments to shareholders (Bakan 2012). Interview data suggests that pharmaceutical companies are now using charities to improve their reputation and strengthen their applications to regulatory bodies. The 2016 Depression Awareness Week campaign WIP was reflective of this change in motive, whereby instead of aiming to influence the actions of patients or practitioners, the focus turned to policy.

Leisinger has written extensively on pharmaceutical industry corporate social responsibility and reputation management (e.g. 2005,2009,2011). However, no research has yet been carried out on the data from charities funded by pharmaceutical companies that is used in applications to regulatory bodies, formularies and policy

makers. The consequences of this newer motivation for pharmaceutical collaboration with charities therefore needs to be explored in more detail.

Part 5: The Present and Beyond

10. Threats

10.1 Introduction

In the 1989 film *Back to the Future II*, Marty McFly and co. travel through time to 2015. The film depicts flying cars, hoverboards and pizza rehydraters. Whilst we have yet to master the art of pizza rehydration, technology has indeed developed significantly since the late 1980s, which also saw the launch of blockbuster antidepressants like Prozac and Seroxat. This thesis began by investigating the history of depression and its treatments, both to better understand current issues and to situate the empirical findings. A narrative emerged. The marketing of treatments consistently corresponds with the marketing of a diagnosis. Or, phrased otherwise, the dominant treatment of the era frames how symptoms of low mood are understood and categorised. Since the late 1980s, SSRIs have been the most popular treatment for depression, and their manufacturers - large pharmaceutical companies - have, in turn, influenced the diagnosis of depression. The success of SSRIs such as Prozac have contributed to the image of Big Pharma as omnipotent and immovable as the leaders in depression treatment. However, throughout history certain institutions and interest groups have enjoyed hegemony over the market for depression treatments, and one-by-one their hegemony, which also seemed invincible at the time, eventually diminished. The adoption of this historical approach has helped to demonstrate that the future of the industry is uncertain. Malerba and Orsenigo (2015) even go as far as to call the current era 'the winter of discontent' for Big Pharma, which may bring about their downfall. Antidepressants have been considered as an analogous case for the wider pharmaceutical industry. This section explores the future of the antidepressant market, and considers the stability of the pharmaceutical industry's position as the manufacturer and distributor of the most popular treatment for depression.

A SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis is commonly used by professionals in the world of marketing and strategy to critically examine the position of a product or organisation in the market. When looking towards the future, the two latter headings become the most important: opportunities and threats. This chapter and the one which follows it outlines the emergent issues coming out of my interviews and documentary investigation, presenting them in terms of opportunities and threats to both the pharmaceutical market and the ability of Big Pharma to market antidepressants as the main treatment for depression.

This chapter explores the threats facing the antidepressant market from two directions: internal and external. Internal threats constitute those factors which tend to push demand away from antidepressants, such as questions over the safety and efficacy of antidepressants. Conversely, external threats correspond to those factors which pull demand away from antidepressants towards non-pharmacological treatments.

10.2 Internal Market Threats

When SSRIs reached blockbuster status in the 1990s, they were deemed by some to be a miracle cure (Kramer 1994). Whilst the public had some reservations about using psychoactive drugs to treat mental illness, disease awareness campaigns were used to change perceptions and reassure the public about the safety of the medicines (See Chapter 9). However, throughout the SSRIs' reign as blockbuster darlings, dissidence brewed beneath the surface. Investigative journalists and critical psychiatrists such as David Healy (2004) identified dangerous side-effects and anomalies in data previously reported. Together, they spearheaded efforts to increase public awareness of these potential dangers.

Throughout the 2000s, Panorama released a series of documentaries looking at SSRI scandals, which possibly helped to create a moral-medical panic around antidepressants (Jofre 2002,2003,2004,2007). These documentaries were praised for initiating an investigation into the link between SSRIs and suicidality in young people. This link had been difficult to prove, as suicidality can also be a symptom of depression. However, over time some healthcare professionals noticed a pattern of some young people engaging in suicidal thoughts and actions after beginning using SSRIs or after having their dose increased. Ultimately, this Panorama investigation culminated in the reanalysis of clinical trial data which demonstrated that GSK actively ignored the suicidal side-effect and excluded it from research papers, all the while attempting to get NICE to recommend their drug for use in adolescents and young people. Panorama also drew attention to the withdrawal symptoms some individuals were experiencing upon ceasing SSRI treatment. Withdrawal symptoms ranged from

gastrointestinal problems to emotional problems. An industry commentator I interviewed spoke of their personal experiences of trying to come off Seroxat (Paroxetine):

I think I was on 30mg a day, yep, 30mg a day and then I thought, well, I'll reduce down to 20mg, that will be a start, because I kind of knew even then, I kind of knew or my wife knew that you really should just stop taking it the way some people try. So, I reduced to 20mg a day and I think it was within four days I was an absolute wreck. I couldn't function, I was tearful, I was all over the place I was absolutely in pieces. And, kind of, we sort of put the two together. It's amazing how you don't actually put the two together very quickly. I went back up to 30mg and within 24 hours I was absolutely fine. So, of course, that set me wondering. I then started to do a little bit of research on the internet. I had purposely avoided that in the past, because I kind of thought if I'm taking Seroxat maybe I want to carry on taking it. I swallowed the line that it's like a diabetic and insulin, you've gotta keep that level of serotonin up. You know, depression it's a medical condition really. Which is an absolute load of bollocks, complete load of tosh.

The commentator went on to recount how they eventually came off the drug nearly two years later:

It took me two years, nearly 22 months to come off Seroxat. Little by little, withdrawing no more than 10% of what I was taking and then stabilising for 2 weeks, 3 weeks, 4 weeks, however long it took, and then reducing another 10%. So, the reductions would consequently get less and less. You know, if I was taking 5mg and reducing by 0.5mg. The only way to do that is to use liquid Seroxat. It comes in a suspension and you use a syringe to measure it more accurately than cutting a tablet. You can't cut a tablet when you get to those last milligrams (Fieldwork Interview, Commentator 1).

Their experience was not unique. Seroxat has a shorter half-life than Prozac and other SSRIs. This means it breaks down faster in the body, which, in turn, makes any reduction in dosage more noticeable than in drugs with longer half-lives. Everyone metabolises compounds differently and so not everyone experienced withdrawal effects when coming off Seroxat, although many did. Panorama drew attention to these stories of withdrawal and side-effects.

The second Panorama documentary in 2003 focused on the over 1,400 emails received after the first documentary aired, drawing further attention to the magnitude and prevalence of the problems people were experiencing whilst taking, and attempting to stop taking, Seroxat. The documentary foregrounded the voices of

people who felt their lives had been affected by Seroxat. One man described finding his teenage son after he had hung himself. A 14-year-old girl recounted engaging in suicidal behaviour and self-harm whilst on Seroxat, which she never did before or after taking the drug:

Cutting myself until I bleed, slitting my throat, walking in front of a bus, all sorts of things going from one extreme to the other really. Stealing a car and driving it off a cliff, jumping off a bridge, all sorts of things (Jofre 2003).

Personal narratives such as these proved extremely powerful. Indeed, the documentaries went on to have a large social impact and have been partially credited with leading to the re-examination of Study 329 (Le Noury et al. 2015). As mentioned previously, Study 329 was a clinical trial conducted by SKB (now GSK) researching the efficacy and safety of paroxetine in adolescence. The published results concluded that paroexetine was 'generally well tolerated and effective for major depression in adolescents' (Keller et al. 2001). However, reanalysis of the study found that paroxetine was not significantly better than a placebo, whilst it also increased the rate of suicide amongst adolescence.

Following on from the success of their prior SSRI documentaries, in July 2017 Panorama released another documentary on SSRIs called 'Prescription for Murder?'. This episode tracked the case of American mass murderer, James Holmes, who killed 24 people in a movie theatre, and questioned whether SSRIs may have been linked to the crime. This possible scandal is not new. However, the Panorama episode helped the idea to take root in the public's consciousness. Panorama producers, contrary to previous SSRI related episodes, chose to focus on one case as opposed to presenting multiple cases and demonstrating a pattern.

The psychiatrist David Healy had been involved in the Holmes case and featured heavily in the documentary, arguing that had Holmes not taken sertraline he would not have committed the crime. Healy has been an expert-witness in a number of cases where antidepressants have been potentially associated with violent behaviour. Moreover, he has collected numerous case studies where an individual has taken an antidepressant in the past, had a bad reaction, and then after taking a higher dosage

of the drug again in the future gone on to commit a violent crime (Healy 2013). I have seen Healy present on this topic, and he predominantly draws on those cases in which the person had no prior history of violence and had already reported experiencing negative side-effects of a SSRI, before later going on to take the drug again and commit a violent act. Healy selects these examples specifically to isolate the effect of SSRIs. Holmes, however, was a much more complex case. Holmes had a history of violent thoughts and had stopped taking an antidepressant weeks before the crime took place. This does not mean that it is impossible that the drugs in some way contributed to the crime, but the strength of the overall argument is weakened by these complicating factors. Furthermore, the documentary lacked the powerful personal narratives of masses of people affected by antidepressant side-effects, which had proved so effective in past documentaries. Instead, it focused on joining the 'dots' up on one, complicated case:

Our investigation of the timeline of events, joining the dots of what happened with his medication, suggests Sertraline may have played a part. We found no evidence Holmes planned to kill before the antidepressants, and plenty to show how afterwards his mental state went rapidly downhill. No one joined these dots up at his trial (Sommers 2017).

Resultantly, the episode has been met with considerable criticism. Media reviews referred to the program as 'propaganda not journalism' due to the magnitude of the claim and the relative paucity of evidence presented to support it.

From the moment I heard about 'A Prescription for Murder', I felt the marketing and the details made available before airing alone was sensationalising the myth that mental health and violence are bound, when in reality all the data available shows the opposite. During the programme itself, I felt demonised. I feel sorry for anyone who sat through last night's show who takes medication or has a family member who uses a SSRI drug, because it was an awful piece of documentary work which I have no doubt will create and inflame stigma around mental health and medication (Woods 2017).

For antidepressant manufacturers, the critical reception of the documentary provided some much-needed relief. However, there was a concern shared by healthcare professionals that the programme may lead individuals to stop taking their antidepressants. Whilst the program actively discouraged this action, this does remain a possibility. Furthermore, the sensationalist title and promotion of the programme could contribute to the stigma associated with taking psychiatric medications, even amongst individuals who did not watch the programme. The program has also been criticised for its irresponsibility in handling the issue of mental health and violence (Sommers 2017). A stereotype exists suggesting that people with mental illnesses are violent, when research suggests that they are far more likely to be the victims of crime than the perpetrators. Mental health campaign 'Time to Change' released a statement following the airing of the documentary:

Media portrayals of mental health problems are very powerful in shaping attitudes and informing people. This is why it's so important to get it right by ensuring the coverage is balanced and provides context. People with a mental illness are more likely to be a victim of violence than a perpetrator, so we are concerned that the Panorama broadcast about medication causing homicidal behaviour feeds into outdated, negative stereotypes and fuels stigma (Baker 2017).

'Time to Change' is run by ReThink Mental Health, who receive less than 1% of their funds from pharmaceutical companies, and Mind, who, as said previously, receive no funds from pharmaceutical companies. Mind had been supportive of Panorama's previous investigations, however, 'Prescription for Murder' failed to garner their support.

I have been unable to find a single positive review of the episode. With the exception of Healy, the medical profession responded negatively to the content of the documentary. Healy (2017) suggests that this may be due to the formation of the Science Media Centre (SMC) organisation, which was set up in 2011 to do the following:

To provide, for the benefit of the public and policymakers, accurate and evidence-based information about science and engineering through the media, particularly on controversial and headline news stories when most confusion and misinformation occurs (SMC 2018).

SMC does not allow corporate donors to make donations which exceed 5 percent of their total donations. However, it does receive large donations of up to £30,000 from multiple pharmaceutical companies. I have not found evidence to suggest that the SMC influenced media coverage of the Panorama episode, and there are multiple differences between the newest documentary and previous Panorama episodes on SSRIs, which, in part, explain the difference in reception. However, investigating the role of the SMC in detail is beyond the scope of this project, although it could be an interesting area for future enquiry.

Thus far, the most recent Panorama investigation of antidepressants has not had the impact of previous episodes. The key thesis of the program was less convincing than that of previous episodes. However, there are other, less high-profile and more straightforward cases which provide more compelling evidence of the possibility that SSRIs can lead to violence in an extremely small number of individuals who take the drug. David Healy leads the push for further investigation into this issue in academic publications (e.g. Healy et al. 2006), in courtrooms as an expert-witness, and in public forums. Healy draws upon a variety of cases to support this argument, such as this example taken from his blog:

David Hawkins was a 74-year-old man with a 20-year history of minor episodes of nervousness, no violence. In one of these he was treated with Zoloft and had a bad response to it. His doctor recorded "Do not give this man SSRIs" ... A number of years later feeling unwell he was seen by a locum doctor who didn't know the history and didn't read the notes and put him on Zoloft. He didn't know that he was being put back on a pill that he had reacted poorly to before. He felt worse after one pill and thinking that more would help took four and the next morning strangled his wife to death. The judge and prosecution agreed with Tania Evers for the defence that, but for the drug, it was unlikely this would have happened (Healy 2013).

Healy typically presents examples where the individual has taken antidepressants before, had a bad reaction, then upon being prescribed SSRIs again later in life, usually at a higher dosage, committed a violent crime. Whilst the sensationalist case presented in Panorama left the audience largely unconvinced, it is possible that Healy's collection of more straightforward case studies could be more convincing. It is

therefore likely that the debate surrounding the link between SSRIs and violence will persist over the coming years, posing a continuing risk for SSRI manufacturers.

10.3 External Market Threats

The pharmaceutical industry has dominated the market for depression treatments since the launch of SSRIs in the late 1980s. Since, the industry has become known as Big Pharma, a seemingly omnipotent entity. At various points across history, the status-quo in the treatment of low mood appeared unlikely to be challenged. However, as discussed in earlier chapters, the condition has been treated under the domain of four humours practitioners, the church, and psychoanalysts at different points in time. hence, it is entirely possible that in the coming decades the treatment of depression will be dominated by different industries. This section examines the external market threat posed by newer industries entering the market, most notably the medical device and tech industries. The commercialisation of mindfulness and its impact on the market will also be explored. This section thus looks at alternative treatments to antidepressants for depression.

10.3.1 The Alternative Market

Although depression is largely a medicalised condition, it also has non-medical treatments. Some of these treatments are used instead of medical treatments, whilst some are used in addition to medical treatments. This section explores commercial treatments for depression which currently fall outside medically prescribed treatments. Whilst these are not necessarily new entrants to the depression treatment market, their popularity has increased in recent years due to cultural shifts.

St John's wort

The herb, hypericum perfortatum, commonly known as St John's wort, is a popular traditional herbal medicine (THM) available over the counter at pharmacies and health food shops. St John's wort is available on prescription in many European countries, however this is not the case in the UK. St John's wort is a THM and, as such, is not subject to the same rigorous testing as standard antidepressants. However, a systematic review did find the medicine to be superior to a placebo and as effective as standard antidepressants in the treatment of mild to moderate depression (Linde et

al. 1996). Although St John's wort is deemed to have a favourable side-effect profile when compared to standard antidepressants, the medicine does interact with many other drugs. Amongst other things, St John's wort can decrease the effectiveness of the oral contraceptive pill and increase the longevity of general anaesthetics. In terms of the market for antidepressants, then, the interactive nature of St John's wort means that it cannot be taken with any standard antidepressants, which, in turn, makes it a potential substitute and competitor in the antidepressant market.

5-Hydroxytryptophan (5-HTP)

5-HTP is a supplement available from high-street retailers such as Boots and Holland and Barret. It is a precursor to serotonin, and once broken down is believed to increase serotonin levels in the brain. UK Google searches for 5-HTP have doubled since 2014 (Google Trends 2018a). In their review of the evidence of 5-HTPs efficacy, Hinz et al. (2012) describe it as seductive. There is an intuitive appeal to taking a 'natural' compound to increase serotonin levels, which has contributed to a dedicated cultfollowing (including Jim Carey) proporting 'exaggerated and inaccurate claims.' However, there is insufficient evidence to suggest that it is an effective treatment for depression when taken alone (Hinz et al. 2012). The appeal of 5-HTP is thus ideological, rather than scientific. Furthermore, 5-HTP is cheaply available online with hundreds of listings on Amazon. Therefore, 5-HTP has the potential to capture wouldbe patients who, after searching online, would rather buy a 'natural' serotonin booster on Amazon than visit their GP to be prescribed an SSRI.

Mindfulness and bibliotherapy

As aforementioned, mindfulness is now being used in combination with CBT as a talking treatment. With its roots in neuroscience, mindfulness is gaining traction within the medical community. However, due to its overlap with concepts from Buddhism and pop-spirituality, mindfulness has also become popular amongst the public. Most recently, this can be seen in the trend of adult colouring books. Mindfulness has been commercialised predominantly by publishers. The evidence-base for self-help books is mixed (Redding et al. 2008). Redding and their co-authors found that, whilst some books were written by authors with medical qualifications whose advice was supported by strong evidence, others lacked any evidence-base at all. One book which draws

upon evidence and has had its efficacy verified in subsequent research, is Burns' (1981) 'Feeling Good: The New Mood Therapy.' Such books have traditionally been thought of as complementary products to antidepressants, rather than substitutions. It has yet to be seen whether this form of mindfulness will buck this trend and become a serious competitor to antidepressants in the treatment of depression, however its popularity is soaring, with Google searches for mindfulness quadrupling since 2011 (Google Trends 2018b).

Formerly Illegal Drugs

Many large pharmaceutical companies have withdrawn from the therapeutic area of depression due to issues covered throughout this thesis: patent expiration, lack of profitability, scandal, and so on. Although many drug manufacturers have withdrawn from the therapeutic area of depression, research is still being conducted into possible helpful compounds. Many of these are not newly discovered compounds, but, rather, drugs which have previously been used recreationally or to treat other conditions. This section focuses on these compounds and the manifold opportunities they present

There are numerous examples of the media promoting sensationalist stories about the use of illegal narcotics to treat depression. Recent headlines include "Party Drug" ketamine really does lift spirits' (Borkhataria 2017) and 'Magic mushrooms "reboot" brain in depressed people' (Siddique 2017). Headlines such as these capitalise on the shock-value of taking these mind-altering substances. However, as frequently noted by Moncrieff, all drugs prescribed to treat mental illnesses are psychoactive drugs, in that they are all mind-altering substances. When this fact is considered, it is far less shocking that drugs such as ketamine and magic mushrooms could have therapeutic effects for some individuals. Referring back to Moncrieff's conceptual framework about drug-based versus a disease-based view of substances, all psychoactive drugs have effects on the brain. Technically speaking, there is no such thing as a side-effect. Simply put, some effects are desired, and some are not. Moncrieff (2008) argues that the main difference between recreational drugs have some pleasurable effects.

Ketamine is known by many to be a horse tranquiliser, as well as often being used by anaesthetists. Early trials have shown that ketamine also had an antidepressant effect in individuals with treatment resistant depression, specifically in reducing suicidality (Price et al. 2009; Murrough et al. 2013). The problem for antidepressant manufacturers is that ketamine is an old compound, and thus cannot be patented and is not profitable. The profit potential for ketamine lies in its mechanism of delivery. There are active and pending patents covering the use of a nasal spray to administer ketamine to treat depression (Charney et al. 2017). It is the owners of these patents who would ultimately benefit from ketamine succeeding as a depression treatment.

Another illegal narcotic currently being researched as a potential treatment for depression is magic mushrooms, more specifically, the active chemical, psilocybin. Two patents for the drug were originally held by UK pharmaceutical company, Sandoz Ltd. (Heim et al. 1965; Hofmann et al. 1965). These patents covered the extraction of psilocybin from the raw material. However, these were both filed over 20 years ago and have since expired.

Probiotics

The vagus nerve, although usually a pair of nerves, is typically referred to singularly within scientific literature (e.g. Borovikova et al. 2000). The vagus nerve links the brain, the heart and the gut. The nerve is one of the largest in the body and is responsible for a vast multitude of bodily functions. Most of the functions of the nerve can be described as 'parasympathetic', meaning that the nerve stimulates unconscious activities linked to the digestive system and sexual function. However, the vagus nerve also causes us to cough if inadvertently prodded with a cotton bud.

Due to the sheer size of the nerve, and its presence in and around many vital organs (vagus literally means 'wandering' in Latin), the nerve can be stimulated a number of ways. In terms of the medical device market, small, hand-held devices have been developed which can be applied externally to the side of the neck. There is also evidence to suggest that the nerve can be stimulated via the digestive tract. In an experiment involving mice, researchers found that the vagus nerve could be stimulated via the ingestion of probiotics, and that mice on the probiotics exhibited less

'behavioural despair' then their control group counterparts (Dinan and Cryan 2013). These findings are very preliminary; however, they do present a possible opportunity in the market for drug manufacturers and 'alternative medicine.'

10.3.2 The Device Market

The device industry is not an entirely new entrant within the market for depression treatments. Anyone who has seen the cult classic 'One Flew Over the Cuckoo's Nest' will remember scenes of patients in pain struggling with the side-effects of electroconvulsive therapy (ECT). ECT is still medically considered as an effective treatment for some individuals with depression, however publicly ECT is often perceived as dangerous. A study by Lauber et al. (2005) found that 57% of respondents considered ECT to be harmful, whilst only 1.2% considered it a treatment. In addition to being inhibited by its public image, ECT fails to prevent future episodes of depression, and, indeed, follow-up treatment with antidepressants is advised. It is for these reasons that ECT has not been a major competitor to the prescription of antidepressants. However, in recent years the device industry has taken a renewed interest in the treatment of depression, and, indeed, companies have been successful in releasing new products to the market.

Vagus nerve stimulation

Medical devices function by stimulating the vagus nerve electronically. This is usually done via a minimally invasive operation, whereby a device is inserted under the skin in the chest under local anaesthetic. The device is activated a few weeks after the surgery, and then, similarly to a pacemaker, the device electronically stimulates the vagus nerve. Although the operation is described as minimally invasive, it is still a relatively serious intervention in terms of depression treatments. Furthermore, the device and its implantation are expensive. Because of these factors, vagus never stimulation (VNS) has thus far only been used in a limited number of patients with treatment resistant depression. This is reflected in the 2009 NICE guidelines on VNS, which only discusses the use of VNS in patients with treatment resistant depression. Therefore, currently VNS is not considered to be a serious competitor to drug treatments for depression.

A counter culture of brain hacking has emerged in recent years (Koch 2010). Brain hacking refers to the use of drugs or, more commonly, electricity to activate and deactivate certain areas of the brain. It is used for relaxation, increased focus and concentration, rapid learning, in addition to recreational purposes. Devices can also be used externally on the vagus nerve; indeed, a US start-up has already developed a hand-held vagus nerve stimulator that they hope will eventually become the first-line of treatment for depression. Therefore, although VNS and repetitive transcranial magnetic stimulation (rTMS) is currently only used in cases of severe treatment resistant depression, it is possible that it could pose more of a threat to the drug market in future years.

Transcranial Magnetic Stimulation

Similar to VNS, transcranial magnetic stimulation (TMS) operates by administering electricity. However, instead of being directed at a pair of nerves, with TMS electricity is administered to areas of the brain via external magnetic stimulation. Thus far, TMS has most notably been used to study the brain by stimulating and suppressing certain areas and monitoring the results. In addition to being a useful research tool, TMS also has therapeutic uses. For example, TMS has been explored as a possible treatment for depression since the 1990's (George et al. 2000). Studies investigating the use of TMS to treat depression initially stimulated the vertex with mixed results. Researchers have also been investigating the possible benefits of stimulating the left prefrontal cortex. In December 2015, NICE released new guidelines advocating the use of repetitive transcranial magnetic stimulation (rTMS) as a treatment option for patients with depression. The guidance notes that one of the advantages of rTMS for patients is that some patients may be able to stop using oral antidepressants. Furthermore, it is important to note that, unlike VNS, the guidelines for rTMS are not limited to cases of treatment resistant depression. Therefore, rTMS appears to be a more serious competitor to antidepressant drug treatment than VNS. Having said this, rTMS is still a new and novel treatment. The interviewed psychiatrists expressed hesitation towards using device treatments for depression, choosing instead to opt for familiar drug treatments and talking treatments. As with VNS, brain hackers are building their own machines for TMS and rTMS at home, however there is hitherto no commercial product available for consumers to purchase.

Transcranial Direct Current Stimulation

Another treatment utilising electrical currents is transcranial direct current stimulation (tDCS). As with TMS, electrical stimulation of the brain takes place externally, and thus tDCS is less invasive than traditional VNS. One benefit that tDCS has over other electrical device treatments, is that it can be done at home. However, research into the efficacy of this treatment is limited; consequently, NICE guidelines request that clinicians inform patients of the uncertain efficacy of the treatment, as well as informing the clinical governance leads of their NHS trust before administering the treatment. Therefore, although tDCS shows promise, once again, it is not presently a competitor to traditional antidepressant treatments.

Previously, the only medical devices that were used to treat depression were the ones used to administer ECT. In recent years, however, the number of new devices being developed and entering the market is far greater than the number of new antidepressants. Although many consider the new developments in medical devices to be promising, in practice the use of these newer interventions is rare.

10.3.3 Apps and technology

As suggested by the name, computerised cognitive behavioural therapy (CCBT) refers to the administration of CBT via a computer program and, in some cases, a telephone. Although they are only now taking off, the idea of using computers to administer therapy is not a new one. In the 1960s, individuals corresponded with a chatterbot named ELIZA (Weizenbaum 1966). A chatterbot is a program which attempts to emulate human conversation. An individual would be able to type to ELIZA and she would respond basically in keeping with a style of psychotherapy known as Rogerian Psychotherapy. ELIZA would function by encouraging the user to vent about their feelings with responses such as 'Can you elaborate on that?' and 'What makes you say that?' Even individuals who knew ELIZA was just a computer program found themselves talking to her for hours about their feelings.

In 2013, NICE updated their guidelines on the use of CCBT. The three programs specified by the guidelines are: Beating the Blues (BtB), COPE and Overcoming

Depression. BtB is specified as an option for individuals with mild or moderate depression, whist COPE and Overcoming Depression are only recommended to be offered as part of a clinical trial. As BtB is the only CCBT program available to patients outside of clinical trial, BtB will be the specific focus of the discussion on CCBT programs. Although BtB was included in the NICE guidelines as a first-line treatment option for depression, none of the healthcare professionals interviewed mentioned considering prescribing CCBT for a patient. In theory, CCBT has an advantage over traditional CBT, in that it is cheaper and does not require the presence and time of a qualified- professional to be administered. However, the NICE guidelines do suggest that sessions are to be completed within a GP surgery, which could go some way to explaining the lack of adoption by GPs. Whilst one of the perceived benefits of CCBT is that sessions can take place at any time of day or night without an appointment, restricting usage to GP surgeries could aid in allowing individuals to remember to do the sessions and motivate them to complete homework, although this practice could also act as a deterrent for some individuals. In addition to being available via the NHS, BtB can be purchased and downloaded from the company website for a discounted price of £49.99 including tax. The legal availability of the program off-prescription could make the treatment favourable to those individuals who do not wish to visit their GP. Those wishing to take antidepressants without visiting a health professional are thus forced to partake in the risky business of buying drugs online. Although there are some advantages to CCBT, the lack of adoption means that treatments such as BtB pose no real threat to antidepressants' market share.

The smartphone has revolutionised many aspects of human life, and when it comes to depression, as the famous Apple tagline goes: 'there's an app for that', or, to be more precise, apps. Another famous tech industry adage is 'move fast and break things.' Resultantly, cyberspace is less regulated than the offline world, which presents numerous opportunities for companies across various fields. Shen et al. (2015) codified the different kinds of depression apps available in the marketplace. Their study found that the apps could be split into: those which provided therapeutic treatment or psychoeducation; those which provided medical assessment; those which provided symptom management; and those which served as a supportive resource. The study only considered apps which specifically mentioned depression, however it is worth noting that other apps which do not directly mention depression are also being used by individuals to aid in the treatment of their symptoms. For example, the app 'Headspace', which provides guided meditations, and similar apps are routinely cited by individuals on depression discussion boards as being helpful.

Traditional therapies and antidepressants are both finite treatments, in that once a tablet has been taken, that same tablet cannot be taken by anyone else. If someone receives an hour of one-to-one therapy, that hour cannot then be used by someone else. In theory, an app can be used by multiple people at the same time without being 'used up'. Although the fixed costs associated with developing a high-quality app can be high, the variable costs which typically arrive with increased users are low.

Apps also have the potential to monitor one's mood and provide real-time interventions in a way that traditional treatments are unable to. For a large portion of society, our phones are with us almost 24 hours a day. As a result, your phone knows things you may never tell a therapist. It knows how long you spent stalking your ex-partner on Facebook, your recent Google searches for symptoms which are probably nothing, but still concern you, as well as the last time you left the house. Moreover, your phone can compare these things with your past behaviour, as it knows whether you are taking longer to respond to texts than you normally do, or whether you are spending more time than normal watching cat videos on YouTube. Whilst the sheer magnitude of data held about each of us on our phones and laptops can be alarming, especially considering how much of this will likely end up in the hands of advertisers hoping to make us offers we literally cannot refuse, it does also have the potential to be helpful.

Currently, no apps for depression have been developed that draw upon this data in any meaningful way. However, such technology has been used to some extent in apps aiming to aid the treatment of addiction. For example, A-CHESS, developed by the University of Wisconsin-Madison, uses GPS to find out when a user is in a high-risk area, such as if an alcoholic is near a store they have habitually used to buy alcohol in the past. The app then alerts the user, encouraging them to stop and think about what they want to be doing. In this instance, the app functions similarly to CBT by disrupting the user's typical behavioural patterns and making them more cognisant of their behaviours.

The American app, TalkSpace, is the closest to traditional talking treatments. Users of the app have access to a therapist who they can message and talk to 24 hours a day. Although the app is based in the US, the 24-hour nature of the service means that it can also be accessed by residents of the UK. Other apps which are associated with the treatment of depression include apps which remind individuals to take medication, meditation and mindfulness apps, and feelings journals. There are currently dozens of depression apps available on Google play store, however the quality and efficacy of these is unclear.

10.4 Conclusion

Over the past two decades, the market for antidepressants has become increasingly crowded. New developments in terms of drug treatments have been rare and failed to recreate the success of blockbuster drugs such as Prozac. As the blockbuster drugs of the 1990's went off-patent, a competitive generics market has arisen causing the cost of SSRI's to fall further. The low cost of existing antidepressants means that expensive newer drugs must outperform old drugs greatly to warrant prescription. Resultantly, the largest pharmaceutical companies have retreated from the antidepressant market place. Current research into the pharmaceutical treatment of depression is turning to existing compounds, such as probiotics, and narcotics like ketamine.

The device industry has produced some more promising innovations in recent years, such as VNS and TMS. Device treatments are currently aimed at more severe, treatment resistant cases of depression, and, as such, do not appear to be a competitor to standard antidepressants. However, with the development of portable devices and an increased move towards 'brain hacking' in certain realms of counter culture, it is possible that such devices could become more commonplace in the treatment of milder depression.

Recently, the practice of mindfulness has increased in popularity in the UK. From the use of adult colouring books, meditation, and even apps, mindfulness is being touted as a form of prevention and potential cure for milder forms of depression (Morgan 2003). Whilst this sentiment is not entirely shared by the healthcare professionals interviewed, there remains some possibility that mindfulness practices could mitigate specific facets of modern life which may be contributing to depression, as emphasised by a GP informant:

I think modern life is probably quite conducive to being anxious or being depressed just because the world is so fast-paced. And I suppose younger people nowadays with the pressures of sort of modern life, technology and things like social media where they always have to be there in the moment, and you're sort of documenting every aspect of their lives, that puts a lot of pressure on them (Fieldwork Interview, GP 1).

Previous chapters have outlined the various paradigm shifts in the treatment of depression, from the church, to psychoanalysis, to the pharmaceutical industry. In each instance, it appeared like the prevailing approach was too big to be overtaken. From scoping out the current market context for depression treatments, it is possible that we are on the brink of another paradigm shift, whereby the device industry potentially takes over the treatment of certain kinds of depression. Whether this will happen or not is unclear. However, what is known is that the market for depression treatments is vastly different from the blockbuster heyday of the late 20th century. So, what does this new horizon mean for the marketing of antidepressants? Are we witnessing what Malerba and Orsenigo (2015) referred to as the 'Winter of Discontent' and the fall of Big Pharma? The next chapter explores the other side of the coin, that is, the opportunities which hint at a more hopeful future (for antidepressant manufacturers at least).

11: Opportunities

11.1 Introduction

The previous chapter highlighted several threats to the future of antidepressant manufacturers based on data gathered throughout the research process. However, the future of the industry is not entirely bleak. Technological advancements, policy developments and societal changes are all creating new opportunities for Big Pharma companies. This chapter outlines these opportunities. Rather than serving as a how-to guide for industry practitioners, this chapter aims to unearth and present the opportunities already identified by a secretive industry by using interview data, industry reports and other documents. This chapter is organised into three sections. Firstly, opportunities from developments within the field of antidepressants will be examined. Secondly, technological advancements in other fields will be presented, and, finally, sociological factors with the potential to favourably impact upon the antidepressant market, specifically in terms of facilitating covert marketing practices, will be presented.

11.2 Response to Previously Identified Threats

The previous chapter highlighted the challenges facing Big Pharma in the treatment market for depression. Threats broadly fell into two categories: questions about the safety and efficacy of antidepressants, and competition from other treatment options. This section considers developments which may reduce the impacts of such threats. Firstly, I discuss the factors which could increase the safety and efficacy of antidepressants or, at the very least, increase the public perception of safety and efficacy. Secondly, I examine the pharmaceutical industry's investment in possible new pharmaceutical treatment options.

11.2.1 Safety and efficacy of antidepressants

"The drugs do work!" exclaimed the Telegraph earlier this year with a headline so creative that it was also used by nearly every other newspaper in circulation (Donnelly 2018). The journalists were referring to a metanalysis conducted by Oxford University researchers which found that, over an eight-week period, antidepressants perform

better than placebos (Cipriani et al. 2018). One of the paper's authors, Professor John Geddes, has since been hitting the media circuit arguing that these findings demonstrate that a million more people in the UK should be taking antidepressants, even though the academic article itself makes no such recommendation. Furthermore, the media coverage of the research was also incorrect in its reporting that pharmaceutical industry funding has no impact on trial outcomes. The researchers found very few non-pharma funded trials, and an increase in reported efficacy for trials which took place whilst the drug was new and novel (Cipriani et al. 2018).

The hyperbolic media coverage led to criticism from prominent figures in the field such as Moncrieff (2018). Moncrieff criticised the methods of the systematic review as it only looked at studies over an 8-week period, whereas in practice people take the drugs for longer. Furthermore, the studies included depression rating scales which inflate changes, such as the Hamilton Depression Rating Scale. Moreover, Moncrieff (2018) questions the usefulness of placebo-controlled trials in psychoactive drugs, because individuals can often tell if they are on the active drug as they may experience side-effects. Moncrieff raises a number of valid criticisms, which are particularly pertinent given the media hype surrounding the research. However, the research is useful insofar as it contributes to a broader evidence-base assessing the efficacy of antidepressants. The research does not tell us categorically that antidepressants work, but the paper does demonstrate that over the course of eight weeks some antidepressants have been found to improve people's depression scores. As Becker (2007) notes, everything tells us something. Furthermore, whether warranted or not, the media coverage may go some way to improve the reputation of antidepressants.

The efficacy of antidepressants could also be improved by individualising medicine. Earlier chapters highlighted how the corporatisation of depression treatments coincided with the homogenisation of treatments. This contrasts quite dramatically with the treatment of depression (or melancholia) in the pre-pharmaceutical/medical era of the late twentieth century. Pre-medicalised melancholia was characterised by Burton (1857) as so diverse that in some cases it could be caused, and in other cases be cured, by more sex. Reading and writing alone could cause melancholia in some scholars, yet Burton used the writing and editing of 'On Melancholia' to alleviate his own symptoms. Throughout the two millennia history of melancholia, its treatment was very much dependent on the circumstance and disposition of the individual experiencing it. However, in the UK today an individual diagnosed with depression will almost certainly be offered an SSRI antidepressant. The treatment of depression has thus become homogenised. In England last year, over 64.7 million antidepressant prescriptions were written, compared with under 9 million contraceptive prescriptions and under 14.5 million non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (NHS Digital 2017). Although, as aforesaid, SSRIs especially are often turned to as the first port of call in the treatment of depression, their efficacy is still questioned. Most studies conclude that the drugs, on the whole, are little better than placebos (e.g. Moncrieff and Kirsch 2015). The lack of efficacy of antidepressants has negatively impacted on the reputation of the whole drug class. In recent years, however, highly publicised-developments in drug tests and DNA testing present an opportunity to increase the efficacy of antidepressant prescriptions, by moving towards more individualised medicine. Jha et al. (2017) found that SSRI response can be predicted by using a blood test which measured inflammation in the brain. Whilst those with higher inflammation did not respond to SSRIs alone, they did respond better to the SSRI when it was used in combination with the anti-inflammatory drug, bupropion.

Currently, only around half of patients will respond to the first antidepressant they are prescribed. If they do not respond to an antidepressant, they will then be prescribed a different type of antidepressant. If the second antidepressant is also ineffective, then a patient is considered to have 'treatment resistant depression' (Al-Harbi 2012), and will often be prescribed a third or fourth antidepressant or combination of antidepressants in the hope that this will lead to improvement. This can be a long process for some patients, because it takes weeks for antidepressants to take effect. Cattaneo et al. (2016) conducted research into the blood-brain barrier, which subsequently found that participants' responses to specific antidepressants could be predicted by a blood DNA test. In the US, the company, Genomind, have already begun offering a DNA test to predict responses to antidepressants and aid clinician prescribing.

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If the use of DNA tests to inform prescribing antidepressants becomes commonplace, it would undoubtedly have some impact on the market for treatments. It is possible that antidepressant prescriptions would increase, as patients will find that the drug they have been prescribed will be more effective, and, as such, they may be more likely to stay on the drug. However, there is also a possibility that this could have a negative impact on the market for antidepressants. Current research does not explore if, when a patient is prescribed a drug which will definitely have an effect, they are also more likely to experience the less desirable side-effects of the drugs.

<u>11.3 Social, Political, Cultural and Demographic Opportunities for Maintaining</u> and Expanding Pharma Market

Thus far in this chapter, the opportunities presented by developments in research and technology have been presented. The culturally iconic status of Prozac exemplifies the interconnectedness of the antidepressant market and wider society. This section examines how sociological changes may impact upon the market for antidepressants.

11.3.1 The evolving diagnosis of depression

Depression has been subject to multiple evolving definitions since the late 19th century (Lawlor 2012). Lawlor (2012) notes that a new, biomedical understanding of depression began to emerge in the 1980s, with researchers believing that depression may be caused by a chemical imbalance in the brain, a model which Lawlor suggests was influenced by the discovery of SSRIs. Similar to how Freud argued melancholia was caused by repressed thoughts, coincidentally the same thing his therapy sought to uncover, the pharmaceutical industry created and promoted a causation of depression which mirrored the treatment they were selling. The idea that depression is caused by a chemical imbalance in the brain is compelling, and entirely within the realm of possibility. However, it has never been proven. Furthermore, the correct 'balance' of chemicals in the brain has never been established either, in part, due to the impossibility of measuring the chemicals in a living person's brain. Therefore, healthcare professionals looking to diagnose this so-called chemical imbalance would have to rely on other methods.

Diagnosing depression is complex, and healthcare professional informants reported relying on intuition and personal experience, in addition to the two, more formal diagnostic criteria for depression: The Diagnostic and Statistical Manual of Mental Disorders (DSM) and the International Classification of Diseases (ICD). The DSM is a US publication from the American Psychiatric Association (APA). The ICD is published by the WHO. Each provides criteria on the diagnosis of depression and is updated every few years to reflect changes.

Changes in diagnosis are common. The mission of the DSM has been to "expand the scientific basis for psychiatric diagnosis and classification" (Kupfer and Regier 2008). However, as succinctly argued by Esposito and Perez (2014), 'the classification of mental disorders is a process that, far from purely scientific, is shaped by political and/or profit-driven objectives associated with the increased corporatization of medicine, including the mental health field.' The inclusion of homosexuality as a mental illness in early editions of the DSM and its subsequent removal in the third edition, is the most commonly cited evidence that mental health diagnoses do not exist in a sterile petri dish. Rather, they are shaped and influenced, as I explore in this chapter, by social, political and economic factors.

In the second edition of the DSM, which was released in 1968, there are four conditions listed in which fragments of what we now call depression can be found: 'Involutional Melancholia'; 'Depressive Neurosis'; 'Manic-depressive illness depressed type'; and 'Psychotic Depressive Reaction' (APA 1968). Each of these diagnoses refers to depression as a symptom but does not make any attempt to define the term. The DSM-II thus exemplifies a transition period, located after the introduction of depression but before the abandonment of melancholia.

The formal diagnosis of depression in the 1990s was published in a revised third edition of the DSM (DSM-III-R) in 1987 (APA 1987). In the DSM-III-R, as with the original third edition DSM-III, depressive disorders were collapsed into one category titled major depressive disorder (APA 1987; Healy 2004, p. 8). DSM-III-R listed several possible symptoms for depression, including depressed mood, fatigue, feelings of worthlessness and recurrent thoughts of death, which could be used as an aid to diagnose the presence and severity of depression.

The most recent version of the DSM is the DSM-V. In the DSM-V, depressive disorders get their own chapter, having previously shared a chapter with bipolar and related disorders. The chapter describes multiple depressive disorders, but notes:

The common feature of all of these disorders is the presence of sad, empty, or irritable mood, accompanied by somatic and cognitive changes that significantly affect the individual's capacity to function. What differs among them are issues of duration, timing, or presumed etiology (APA 2013, p. 155).

The DSM-V criteria for major depressive disorder is unchanged from DSM-IV. However, there is one major amendment in the notes beneath the criteria. Earlier versions included a caveat which specified that the criteria were not applicable to someone experiencing the early stages of grief, for whom depressive symptoms may be a normal part of the grieving process. The omission of this caveat was controversial. Critics argued that it was an example of 'over-medicalisation' and a result of the APA being too cosy with pharmaceutical companies (Cosgrove and Krimsky 2012). In the text, the authors directly refer to antidepressant treatment:

Bereavement may induce great suffering, but it does not typically induce an episode of major depressive disorder. When they do occur together, the depressive symptoms and functional impairment tend to be more severe and the prognosis is worse compared with bereavement that is not accompanied by major depressive disorder. Bereavement-related depression tends to occur in persons with other vulnerabilities to depressive disorders, and recovery may be facilitated by antidepressant treatment. (APA 2013, p. 155)

To aid medical professionals in differentiating grief from depression, the DSM-V contains the following footnote:

In distinguishing grief from a major depressive episode (MDE), it is useful to consider that in grief the predominant affect is feelings of emptiness and loss, while in MDE it is persistent depressed mood and the inability to anticipate happiness or pleasure. The dysphoria in grief is likely to decrease in intensity over days to weeks and occurs in waves, the so-called pangs of grief. These waves tend to be associated with thoughts or reminders of the deceased. The depressed mood of MDE is more persistent and not tied to specific thoughts or preoccupations. The pain of grief may be accompanied by positive emotions and humor that are uncharacteristic of the pervasive unhappiness and misery characteristic of MDE. The thought content associated with grief generally features a preoccupation with thoughts and memories of the deceased, rather than the self-critical or pessimistic ruminations seen in MDE. In grief, self-esteem is generally preserved, whereas in MDE feelings of worthlessness and self-loathing are common. If selfderogatory (sic) ideation is present in grief, it typically involves perceived failings vis-à-vis the deceased (e.g., not visiting frequently enough, not telling the deceased how much he or she was loved). If a bereaved individual thinks about death and dying, such thoughts are generally focused on the deceased and possibly about "joining" the deceased, whereas in MDE such thoughts are focused on ending one's own life because of feeling worthless, undeserving of life, or unable to cope with the pain of depression. (APA 2013, p. 161)

The idea that grief is experienced differently by different people is well-established. Following on from this, the concept that a small number of people experiencing grief may be affected in such a way that they meet the criteria for a major depressive episode is not absurd. However, whether such individuals require a diagnosis of depression remains questionable.

During the development of the DSM-V, articles were published advocating for the inclusion of a diagnosis for Prolonged Grief Disorder (PGD) (Prigerson et al. 2009) and Complicated Grief (CG) (Lichtenthal et al. 2004). Part of Lichtenthal et al.'s (2004) argument for the inclusion of CG is that healthcare professionals are diagnosing grieving people with depressive disorders and post-traumatic stress disorder (PTSD), although, as the authors explain, literature on grieving characterises it as different to both these. Lichtenthal et al. (2004) argue that CG can lead to poor health outcomes and suicide in some people, which warrants further research. They argue that to conduct research into this area, formal diagnostic criteria must first be established. I was unable to find pharmaceutical industry connections for any of these authors, and they do seem to advocate for further research into talking treatments for CG, rather than purely pharmacological ones.

Prigerson et al.'s (2009) paper on PGD paints a similar picture. PGD should be differentiated from other conditions and have its symptoms specified. Furthermore, the authors use empirical evidence to demonstrate early predictors of PGD, suggesting the use of psychotherapy soon after death to aid in a normal grieving process. Of the paper's nineteen authors, only the eighteenth author listed, Michael B. First has

pharmaceutical industry ties. In the five years prior to the publication of the paper, First had done paid consultancy work for eight pharmaceutical companies.

These papers are indicative of a push to separate abnormal responses to grief from existing diagnoses. They also abstain from advocating the pharmacological treatment of grief, instead suggesting prevention and treatment may be aided by talking treatments. These papers are the most cited, most engaged with papers on the DSM-V and grief. The APA prides itself on using empirical evidence to support its DSM editorial decisions, which begs the question: why did the APA respond by providing guidance on how to diagnose depression in grieving people, and why does the DSM explicitly refer to antidepressant treatments in these cases?

When a new version of the DSM is being created, a panel is formed by the APA to assess the evidence and decide what changes, if any, should be made to diagnoses. Of the panel formed to assess the Mood Disorders chapter, 67% had ties to pharmaceutical companies who manufacture treatments for mood disorders or companies that service the pharmaceutical industry (Cosgrove and Krimsky 2012). Cosgrove and Krimsky (2012) obtained information on the interests of panel members via the APA's disclosure policy. However, the policy does not require panel members to disclose 'unrestricted research grants,' meaning that the actual percentage of panel members with industry ties could be even higher. Furthermore, there is no evidence that a large, unrestricted research budget from a pharmaceutical company protects individuals from bias. Conversely, research published on the outcomes of such research suggests that it makes authors more likely to publish positive results (Lundh et al. 2015).

It is therefore entirely possible that the exclusion of a grief caveat in the DSM-V, rather than constituting a separate diagnosis or an abstention from wholly medicalising grief, is a result of a biased panel. That is to say, the decision reflected the interests of the pharmaceutical industry, particularly in its specific reference to antidepressant treatments. This discussion about the contemporary diagnosis of depression serves to reinforce Esposito and Perez's (2014) point that the classification of mental
disorders is shaped by political and/or profit-driven objectives associated with the increased corporatisation of medicine, including the mental health field.

11.3.2 Privatisation and neoliberalism

Although it is often considered the 'jewel in the crown' of the UK, the future of the NHS is by no means certain. Previous chapters have highlighted a pattern of covert privatisation. NHS budget cuts create space for pharmaceutical industry involvement in areas such as disease awareness and continuing medical education. There are however, also indicators that privatisation is occurring via overt, formal pathways. This section firstly presents the evidence that points to increased privatisation in the UK, before proceeding to explain why a private healthcare system represents opportunities for antidepressant manufacturers.

Pollock and Roderick (2015) point to the Health and Social Care Act (HSCA) 2012 as marking the end of the NHS in England. For decades, Pollock has published papers exploring the rationale for policies which invite privatisation, such as the Private Finance Initiative (PFI) in 1992. The PFI allowed old outdated hospital buildings to be refurbished with private investment, however it has since resulted in increased NHS spending. The HSCA 2012 was a controversial government act established on 1st April 2013, with the intention of reforming the NHS. The HSCA introduced new powers with the express intent of facilitating the introduction of future policies geared towards 'Making the NHS more efficient and less bureaucratic' (Department of Health 2013b) and 'Helping people make informed choices about health and social care' (Department of Health 2013a). This focus on efficiency and choice contributed to the perception that the act was a veiled attempt to begin privatising the NHS. Prior to its enactment, the HSCA was criticised heavily by academics who drew upon empirical evidence to argue that the act should be dismissed (e.g. Greener and Mannion 2006). However, the evidence presented was ignored, resulting in claims that the act was, in fact, a vehicle through which to covertly move Britain towards a neoliberal political model (Pownall 2013). The impact of growing neoliberalism will be discussed further later in this section.

One of the principal points of contention with the HSCA was the reintroduction of general practitioner fundholding. General practitioner fundholding refers to the phenomenon whereby 'general practitioners are given budgets from which they purchase services for patients' (Petchey 1995, p. 1139). Popularised in the early 1990s, the primary aim of GP fundholding is to increase the efficiency of care by making GP's accountable for how funds are spent. However, the Cochrane Collaboration's systematic review of the effects of general practitioner fundholding in the UK found no evidence to suggest that there was a significant relationship between fundholding and reduced drug spending (Sturm et al. 2007). Rather, as Pollock (2015) notes, the act has resulted in a fragmented, inefficient system, with an increasing dependence on private funds.

In addition to explicit policies which have contributed to the increased privatisation of the NHS, previous chapters have outlined how privatisation can occur via other means. Most notably, cuts to training budgets create space for pharmaceutical companies to move in. While politicians are drawn to issues that curry favour with voters, such as waiting lists, training budgets are being cut which leaves space for pharma-funded education:

If you work in the NHS, we get no funding for training at all. Zero ... so, the drug reps will sponsor these speakers to come and speak and talk to us and do training, so I know some drug reps through that anyway and I know that some of them have a stand at the conference as well, so they're quite happy to support people to attend the conference, to support training and development of staff ... It's about training and if I wasn't to receive this support from the pharmaceutical industry then I would struggle with a lot of my own CPD, and it's not just about the training, it's about peer-support, about learning good practice from other people. There's so much more you can get from getting to these meetings, so if it wasn't for the pharma industry I probably wouldn't have attended the majority of them. So, you know it's thanks to them that I have. And I don't think that by attending I have been persuaded to use their drugs more than others or anything (Fieldwork Interview, Pharmacist 8).

Through cutting training budgets, some healthcare professionals feel forced to obtain their education from private sources, mainly pharmaceutical companies. In a similar way, we see creeping privatisation across various areas of the NHS. The HSCA of 2012 opened the doors for increased privatisation via policies such as GP fundholding (Pownall 2013). Although the increasing privatisation of the NHS has been met with widespread criticism, a private healthcare system in the UK could be beneficial for antidepressant manufacturers. In the UK, one of the closest analogies we have for a private healthcare system is car mechanics. This is a private industry characterised by information asymmetry. The term information asymmetry is used by economists to describe a market where there is a large gap in knowledge and expertise between the customer and the seller. Taking your car to the garage can be a stressful experience, partly because a power imbalance exists in the form of information asymmetry between myself and the mechanic. The mechanic has expertise; however, they also have a financial interest in selling more products. As a white woman, the privilege I experience when going through airport security is turned on its head at the garage. I was recently quoted £300 for a repair which would require ordering parts in one colour and painting them white. When my father took the same car to a garage he was charged £80 and the parts could be ordered in white. The information imbalance between myself and the mechanic was perceived to be large, thus creating an opportunity for the mechanic to try to sell me services I did not need.

Information asymmetry favours sellers, as it allows them to overcharge and sell redundant products and services (Vining and Weimer 1988). As Vining and Weimer (1988) note, this reduces economic efficiency, which is why it is considered one of the four traditional forms of market failure. Market failures are usually pointed to as areas which warrant public interventions; for example, the 'invisible hand,' if left to its own devices, would never build a lighthouse. The market failure generated by information asymmetry is evident in the US healthcare system, which is the most expensive in the world and yet yields the poorest outcomes of any high-income country (Schneider and Squires 2017).

Consequently, more medicine does not always mean better outcomes; sometimes it means poorer outcomes (Glasziou et al. 2013). However, a private healthcare system driven by the profit motive always errs on the side of more medicine. This is evident in the US healthcare system. Expensive tests will be ordered 'just in case', benign lumps will be removed without question, and medicines are prescribed far more freely than in nationalised systems. The 'too much medicine' problem is epitomised by a

retrospective analysis conducted by Jena et al. (2015), who found that mortality rates improved among patients hospitalised with heart conditions during national cardiology meetings, because heart surgeons were out of town that weekend and unable to perform emergency operations. Rather than take place on Monday when the surgeon returned, it was found that these operations did not actually need to take place, which led to improved health outcomes.

Antidepressants are already prescribed in the UK at a high-rate, however the price sensitivity of the NHS means that almost all of these prescriptions are for cheap generic drugs. However, private healthcare system features, such as information asymmetry and 'more medicine', create an opportunity for sales of branded, more expensive drugs. This idea is supported by a psychiatrist informant, who noted that agomelatine, whilst unsuccessful at reaching NHS patients, is very popular amongst UK private practitioners:

It's the favourite antidepressant in all of private practice ... Almost every local primary care organisation, the CCGs, they have not approved it for GP use ... So, it's just never happened but where people are paying for it themselves, and it costs just under 30 pounds a month and the 25mg dose people are prepared to pay for it. The little bit of private work I do, it's the favourite drug and it's, you know, going through the pros and cons of all the medication it's the one that most patients would choose because of the side-effect profile, and it's more powerful than the standard SSRIs ... in the private sector its very popular (Fieldwork Interview, Psychiatrist 6).

Privatisation has the potential to increase access to patented antidepressants, therefore providing an opportunity for antidepressant manufacturers. Further to this, privatisation is a neoliberal tool, in the sense that it is both indicative of, and contributes to, what McGregor (2001) refers to as a neoliberal mindset. Such a mindset favours individualism and competition, which, in turn, creates further potential opportunities for the antidepressant market.

Esposito and Perez (2014) also discuss the sociological implications of neoliberalism and their impact on mental health. In a neoliberal society, happiness is associated with success and prestige. A neoliberal society therefore problematises depression and, due to the individualism that characterises such societies, locates problems within the individual. Depressed people are thus pathologised as 'self-contained agents' (Esposito and Perez 2014). The impact from social problems which the market fails to address, such as loneliness in the elderly, the isolation of disabled people, and the stress associated with job intensification, are ignored. The UK is already a capitalist society, and, as such, these aforesaid issues are already familiar. However, as a neoliberal tool, the privatisation of healthcare has the potential to intensify the 'obsession with medicalization' (Esposito and Perez 2014:414). A GP informant described an increasing trend for individuals wanting to be medicalised:

I think there is a shift, in I think people do tend to be more wanting to explain behaviour through medicalisation. I think there seems to be this consumerist approach to healthcare where any sort of emotional instability, not always sort of, I think sometimes when you say this it sounds unfair, but I think people interpret melancholy or just being slightly sad, which, you know all humans have fluctuations in mood, but people often medicalise that and explain it as depression which is, obviously, is a diagnosis and perhaps when they sort of enter the sick role and they have some validation for that symptom. When, in fact, actually it's probably low-grade sort of, you know, fluctuations in mood. So, I think lots of factors are cultural and societal (Fieldwork Interview, GP 1).

11.3.3 Social Media and the Digital Pharmaceuticalisation of Depression

One of the core arguments of this thesis, is that whist concepts such as medicalisation, pharmaceuticalisation and disease mongering prove incredibly useful when analysing the marketing of antidepressants before the mid-2000s, more recent behaviour is better understood as covert privatisation. Covert privatisation explains why pharmaceutical companies continue to fund disease awareness campaigns and continuing medical education. This privatisation allows pharmaceutical companies to promote their products without engaging in overt, unethical techniques such as flying doctors to Australian islands. However, disease mongering has not been eradicated completely. Rather, as with many socially undesirable activities, it has moved online.

In the UK, it is illegal to advertise prescription medications directly to the public. However, the global nature of the internet is blurring these boundaries. Via the internet, UK patients have access to information from other countries, including foreign adverts for medications. Furthermore, companies have social media accounts where they frequently post information about the disease areas they work in. For example, as Lundbeck are the only company currently actively marketing an antidepressant, they have several YouTube videos on depression. Earlier this year for World Health day, they posted a video titled 'What is depression?' The video comprised senior Lundbeck employee, Thomas Brevig, explaining what depression is (H. Lundbeck 2017). He notes that depression is very common, affecting around 350 million people globally. Brevig proceeds to say 'It's a brain disorder, so there's chemical imbalance in certain areas, certain systems in the brain, and they can express themselves in different ways. So, there's emotional, cognitive, and physical symptoms.' As he says this speech, bubbles pop-up next to him saying 'cognitive symptoms, emotional symptoms and physical symptoms'. The unique feature of Lundbeck's newest drug is that it aims to treat symptoms of cognitive dysfunction in depression. Most interestingly, however, is the video's framing of depression as a chemical imbalance, as the chemical imbalance theory of depression still has yet to be supported by evidence. Lundbeck's video demonstrates that companies can use their social media presences for disease awareness activities and to prioritise information which is favourable to their marketing objectives. At no point in these videos does the company promote their medications; however, they do emphasise the cognitive dysfunction symptom and the disease burden of depression.

Moreover, patients are increasingly using forums and social media to discuss their medications. With all psychoactive medications, there is a longstanding issue of adherence. Patients may experience side-effects and stop taking their medication, or simply not feel that the medication is making a difference. In terms of traditional marketing theory, this could be conceptualised as cognitive dissonance. As well as promoting the initial purchase and use of a product, marketing and advertising can be used to reduce cognitive dissonance. This is most common in the new car market, where adverts serve more to settle the worries of people who have already made the substantial purchase of the car, rather than speaking to individuals looking to buy a car. Similarly, the internet provides an opportunity for companies to spread positive information about their product globally. Individuals experiencing side-effects may search on Google for information on their drug. Patients may then be reassured that the side-effect may not last, or that the drug will become more efficacious over time

and thus choose to continue taking the drug, whereas in the past the cognitive dissonance could have caused the patient to cease treatment.

Social media is also reducing the stigma associated with mental illnesses. Tumblr is a microblogging platform where users share media such as videos, blog entries and pictures to their followers. Perhaps most famously, Tumblr was responsible for #TheDress, a viral post which asked users whether a dress was blue and black or white and gold. The post ultimately brought attention to the scientific theory of colour constancy, where the brain takes cues from the surrounding context of an object to decide its colour. However, above all, it demonstrated the power of Tumblr, and how posts on the site can spill over onto more popular social media sites.

There is a large community of mental health advocates on Tumblr, many of whom have mental illnesses themselves. The community is so prominent, and so active in its work, that Tumblr has been accused of glamorising mental illness (Bond 2012). Some users list their diagnoses (sometimes self-diagnoses) on their page, an activity perceived by some as stigma reducing, whilst others see it as romanticising mental illness.

At the most extreme end of the spectrum, the site has been used by individuals to explicitly promote mental illnesses, most notoriously, tags which provide advice and motivation to encourage individuals with eating disorders to be as unwell as possible. Such pro-eating disorder content has been accessible on the internet since the 1990s. However, as Tumblr caters towards subcultures which are easily accessible via tags, the platform has become a key host of such content. Whilst Tumblr has tried to censor such content, the platform has still been used to share images of self-injury (Lewis and Seko 2016).

Mental illness and identity have been discussed and explored by sociologists for decades, particularly in relation to stigma (Goffman 2009). However, mental health diagnoses can also be a profound source of comfort and pride for some individuals (Yanos et al. 2010). This has been identified in academic literature, however it is

perhaps best articulated during a musical number from the television program, *Crazy Ex-Girlfriend*:

A diagnosis! A diagnosis! Don't tell me "No, sis-Ter, you don't fit in." Doc, prescribe me my tribe, give me my throng Tell me that this whole time I've belonged With those other people who share my diagnosis... ...I'm aware mental illness is stigmatised But the stigma is worth it if I've realised Who I'm meant to be, armed with my diagnosis (Bloom 2017).

As Tumblr users list their diagnoses on their profile and tag their posts with condition names, such as #depression, they are easily identifiable to anyone who wants to search based on that criteria. For this reason, trade blog pharmaexec.com noted that 'What you will find when you take a closer look at Tumblr is a lot of potential patients' (2013).

In 2013, the pharmaceutical company, Janssen Therapeutics, created the Tumblr page 'Positively Together' to engage with the Tumblr community living with HIV. The page invited users to upload stories of their experiences with HIV, ticking a box to confirm whether they were over 18 and lived in the US. Although contributions were only invited from US adults, due to the global nature of Tumblr the page was visible to users across the world. In short, the increasing propensity of people to use Tumblr to document their mental health makes it a potentially useful platform for pharmaceutical companies.

11.5 Conclusion

The 'fall of Big Pharma' (Malerba and Orsenigo 2015) is not inevitable. Although changes in the market have increased competition for antidepressant manufacturers,

and reduced the profitability of the treatment area, there remains considerable opportunities for the future. Medical and technological developments, allied with societal changes, means that the antidepressant market may morph and grow in the future. Whilst these opportunities are indicative of factors which could improve the profitability of antidepressant manufacturers, they do not necessarily translate as opportunities for broader society. Privatisation is the principal example of a process which provides exciting opportunity for companies, whilst the evidence-base suggests that it potentially decreases societal health and wellbeing.

12: Conclusion

12.1 Introduction and Synopsis of Thesis

Through exploring existing literature on antidepressant marketing, I identified that new research was necessary. There was a paucity of input from business management, despite the field being defined by large organisations. Once I made the decision to dedicate my thesis to addressing this need, numerous decisions about the methodological approach had to be undertaken. The methods chapter documents this decision-making process, and the choices that were ultimately made. Examination of methodological literature led me to decide upon a novel, investigative approach that draws on the work of investigative journalist, Mark Lee Hunter (2011), in addition to traditional academic scholars such as Derek Layder (1993), Michael Billig (2013) and Howard Becker (2007).

The structure of the findings chapters have been heavily inspired by Derek Layder's (1993) approach to structuration. He argues that history is a method in its own right, and, as such, that history and context should permeate every aspect of the research process. In the spirit of investigative social science, the structure has also been influenced by investigative journalism, particularly the narrative focus of Story-Based Inquiry (Hunter 2011). Drawing on each of these approaches, the first two findings chapters focused on the intertwining historical narratives of depression and its treatments. Analysing these highlighted a pattern that depression has been consistently defined by those with proposed treatments. The conclusion of this section took us up to the point where depression was being predominantly defined by pharmaceutical companies. The next section picked up and ran with this narrative, in a historically sensitive Layder-esque fashion, by examining the industry which manufactures pharmacological treatments for depression. Once the history of the industry had been established, Chapter 7 honed in on the front-line of pharma marketing efforts: PSRs. The concept of 'Dirty Work' was used to understand the omission of 'pharmaceutical' and 'sales' from PSRs' job titles. Later in the chapter, I examined the extent to which PSRs manipulate prescribers to increase antidepressant sales. Ultimately, I concluded that, whilst reps are no-longer allowed to use gifts and excessive hospitality to influence healthcare professionals, they continue to engage in

personality typing to 'better communicate' with healthcare professionals. Techniques which have been publicly criticised have thus changed and improved with increased regulation, however, as explained by Abraham's (2008) 'neo-liberal corporate bias', regulation is predominantly self-serving and reactive. Consequently, activities invisible to the public, such as personality typing, targets and bonuses, remain unregulated.

The following section looked outside of the industry, to its customers and collaborators. Chapter 8 focused on healthcare professionals. Healthcare professionals occupy multiple rolls in the antidepressant supply-chain. They are the gatekeepers, standing with prescription pads between antidepressant manufacturers and patients, and, on a larger level, writing formularies and prescribing guidelines. In their role as gatekeepers, they are also the lucrative targets of antidepressant marketing. However, they also interact with the industry as collaborators, advisers and students. Through drawing upon interviews with 28 healthcare professionals, the chapter explored the complex and changing relationship between healthcare professionals and the pharmaceutical industry. I looked back at the iconic BMJ cover which depicted healthcare professionals as greedy pigs eating at the Big Pharma trough and questioned to what extent this is still the case. Informants recounted being flown to exotic islands by companies during Prozac's blockbuster heyday, whereas more recent interactions were less lavish. Rather than being motivated by greed, the main driver of interaction with pharmaceutical companies was knowledge. In the same way that healthcare professionals are gatekeepers of prescriptions, through NHS budget cuts pharmaceutical companies have become the gatekeepers of knowledge. Some informants described how they felt stuck in a catch-22 situation, in which they must choose between receiving biased information or no information at all.

As was found in the previous chapter, regulation has improved the ethical status of interactions between healthcare professionals and the pharmaceutical industry. However, regulation has failed to 'untangle' this relationship in the exact way called for in the BMJ special issue, as fully untangling would require removing the conflict of interest posed by industry-funded information. Instead, healthcare professionals' continuing medical education, information resources, and clinical trials would all need to be independently funded.

Chapter 9 looked at the oft-overlooked organisations who work to increase awareness of depression. The first depression awareness campaign in the UK was the DDC launched in 1992. The campaign is often referred to in critical literature as a turning point for depression and its treatment (Healy 2004; Moncrieff et al. 2005). Funded by the manufacturers of Prozac and Seroxat, the campaign was criticised for being biased. Most notably, Eli Lilly funded a survey which found that 74 percent of the believed antidepressants were addictive. The population assertion that antidepressants were not addictive then subsequently became a key message of the campaign. Examination of archival material found that the organisers of the campaign were routinely questioned about the basis for this core message and asked for evidence and clarification. However, the message remained unchanged, and years later it became clear that antidepressants, particularly Seroxat, could cause dependence in some people.

Later campaigns were dominated by the charity DA, who ran depression awareness week. When depression awareness week occurred around the time of a new antidepressant looking to gain marketing approval, the week would centre around a report. In 2005, the report emphasised the role of aches and pains in depression. It was funded by Eli Lilly, the manufacturers of Cymbalta, an antidepressant which was recently approved to treat neuropathic pain. Similarly, the reports used in 2006 and 2007 depression awareness weeks were funded by Lilly and emphasised pain. In 2008, a report called 'The Inside Story' was released by DA and funded by Servier. Servier manufacture the antidepressant, Valdoxan, which is similar in structure to melatonin and regulates sleep. The report that year, and the media coverage surrounding it, emphasised the role of sleep in depression. Campaigns up to this point thus reinforced the narrative identified earlier in the thesis, that depression is defined by those who are promoting a treatment. More specifically, however, these campaigns can be characterised as pharmaceuticalisation and disease mongering, as they promoted and broadened the symptoms of depression, influenced by pharmaceutical funding.

The most recent depression awareness weeks in 2015 and 2016 were also funded by pharmaceutical companies. These centered on a report funded by Lundbeck called

WIP. Lundbeck's newest antidepressant is called Brintellex, and its key point of differentiation from other antidepressants is that it also treats cognitive dysfunction. Again, as with previous chapters, we see an improvement in the ethical status of industry activities, as The WIP report does not over-emphasise the symptom which Brintellex uniquely treats. Disease mongering has been criticised in pharma-funded disease awareness campaigns (Seroxat Secrets 2005; Moynihan and Henry 2006; Seroxat Secrets 2008), which is harmful to the reputation of pharmaceutical companies as it makes them less profitable.

Pharmaceutical companies are private entities which are required to make a profit. The chapter concluded by utilising Loseke's (1997) idea of political and rhetorical power to demonstrate that, particularly in the wake of scandals, pharmaceutical companies seek to improve their reputation through associating themselves with charities. Furthermore, the political power of charities has the potential to positively influence decision-making at an altogether higher level than disease mongering campaigns – the realm of politics.

The final section acts as a bookend to the first. This thesis began by looking towards the past, and ended with examining contemporary issues in the antidepressant market. This thesis has demonstrated that, whilst depression has historically been framed by those offering a treatment, throughout history the era defining treatment eventually subsides and is replaced. It is therefore entirely possible that antidepressants will be replaced as the treatment du jour. Chapter 10 highlighted the threats to antidepressants dominant position within the depression market. The two major points that emerged centred on the fact that, firstly, the safety and efficacy of antidepressants is constantly under question, and, secondly, that other treatment options are being developed and increasing in popularity. Chapter 11 examined contrary evidence, such as newer studies that suggest that antidepressants are effective and the possibility that efficacy will increase as medicine becomes more individualised. Finally, the sociological landscape and the ways in which it could benefit antidepressant manufacturers were discussed. Ultimately, the conclusion is that there may just be life in the black dog yet.

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12.2 Evaluating the Contributions of this research

This thesis offers a range of unique contributions to extant literature. Firstly, this study represents the first research into antidepressant marketing from within a school of management. The literature review demonstrated the need for business researchers to engage with this topic, and this thesis goes some way to addressing this gap. This research has also demonstrated the applicability of investigative social science for business research. The business world is dominated by large powerful organisations who are either likely to deny access or use their power to place stipulations when access is allowed. Therefore, when applied to business and management research, an investigative social science approach allows for the investigation of topics and issues which might otherwise have been avoided due to access issues. Dunne et al. (2008) found that business management consistently failed to engage with important sociological issues. Utilising an investigative methodology allows researchers to better engage with issues of social significance and serve the community as public intellectuals (Marinetto 2015). Adding investigative social science to the menu of methodological options available to business management researchers, thus allows scholars within the field to better address social problems. This research has demonstrated that combining aspects of traditional social science and investigative journalism can be successful in examining issues of broad social significance, such as corruption and mental health. The richness of data which was obtained via semistructured interviews – the bread and butter of many qualitative researchers - was complimented by an 'open source strategy' (Hunter 2011, p. 31) lifted from investigative journalism.

In addition to its methodological contribution, this thesis also contributes to the empirical landscape of the field. It is the first qualitative investigation into the Disclosure UK database and the first academic investigation into DA. Resultantly, this research has produced findings which are novel to the field of pharmaceutical industry study. I have been able to demonstrate that the ethical status of antidepressant marketing has improved in several areas, including depression awareness campaigns, hospitality and gift giving. However, I have also drawn upon Abraham's (2009) notion of neo-liberal corporate bias to explain how, whilst activities have improved, such improvement is distorted by the requirement to make a profit. Furthermore, through

engaging with history in a meaningful way, this research has identified a trend of depression being consistently framed by those who are promoting a treatment. This narrative has been reinforced by data gathered throughout this investigation, and, as such, provides a framework through which to explore future innovations in this treatment area. Furthermore, this research has contributed to Conrad's (2005) argument that medicalisation is driven by pharmaceutical companies, through its examination of the business practices contributing to the medicalisation of depression.

12.3 Limitations and Recommendations for Further research

The release of the 2015 Disclosure UK database was a key turning point in this research. It enabled me to contact several healthcare professional informants who were in direct contact with antidepressant manufacturers. Since finished data collection, and began writing up this thesis, the data for 2016 and 2017 have been released. The BMJ have done an excellent job of analysing the data quantitatively in each instance, however this research has demonstrated that a deeper qualitative investigation that goes beyond the figures can be useful. In-depth interviews with informants from the database uncovered alternative motivations for collaboration with pharmaceutical companies that went beyond the infamous 'greedy pig' image. More qualitative studies into the Disclosure UK database would thus allow for further exploration of the motives and experiences of healthcare professionals who chose to engage with industry. Further research into this phenomenon could influence policy guidelines impacting upon such relationships, in addition to helping policy makers to address the negative factors pushing collaboration, such as the reduction of training budgets in recent years.

12.4 Concluding thoughts

This thesis represents the first research into antidepressant marketing from a business management perspective. Incorporating business knowledge and ideas with sociomedical phenomena, such as pharmaceuticalisation and medicalisation, has allowed this thesis to contribute to two distinct bodies of literature: business management and socio-medical. Conrad (2005) noted that medicalisation is now driven predominantly by pharmaceutical companies. Abraham (2010) coined the term pharmaceuticalisation to describe medicalisation driven by pharmaceutical companies. This thesis has contributed to these ideas by exploring the business management activities through which companies drive medicalisation/pharmaceuticalisation. Overall, the research has found that, although regulation has improved, and less overtly unethical marketing practices are now used to promote antidepressants, pharmaceutical companies are still able to covertly influence the diagnosis and treatment of depression. For example, companies can still fund continuing medical education, industry employees still determine diagnostic criteria and fund disease awareness. It is tempting to place the blame for pharmaceuticalisation entirely at the feet of the pharmaceutical companies themselves. However, as demonstrated throughout this thesis, these activities are consistently enabled by government. An underfunded NHS creates a vacuum which will be filled by those who profit from doing so: pharmaceutical companies.

Pharmaceutical companies are companies. We want them to behave morally because they have our lives in their hands. Perhaps we should see them in the same way that the informant who trained PSRs saw them: cornflake sellers.

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Appendices

| | Appendix A | A: Table | of Informant | S |
|--|------------|----------|--------------|---|
|--|------------|----------|--------------|---|

| Name | Notes |
|---------------------------|---|
| Charity Worker 1 | Surprisingly, I found workers for charity organisations most difficult to arrange interviews with. After some failed attempts to contact this informant via charity email addresses and phone numbers, I was able to contact them through a company I discovered they owned on Companies House. It was a medical PR company servicing the pharmaceutical industry. This was the last interview conducted for the thesis. |
| Industry Commentator 1 | All three industry commentators were contacted via |
| Industry Commentator 2 | Commentator 1 was difficult to contact as they work |
| Industry Commentator 3 | hard to keep their identity anonymous, however I was ultimately able to get contact information for them via commentator 2. |
| Medical PR Professional 1 | |
| Medical PR Professional 2 | |
| Medical PR Professional 3 | |
| Medical PR Professional 4 | |
| Medical PR Professional 5 | |
| PSR 1 | Expecting them to be the most difficult to contact, I |
| PSR 2 | manage their own schedules they were the easiest |
| PSR 3 | group to arrange interviews with. PSRs 1 – 4 all |
| PSR 4 | entered the profession directly norm driversity. |
| PSR 5 | Both this PSR and PSR 7 began their careers in nursing. Their path to becoming PSRs involved a hybrid role. As nurses, they applied for 'nurse advisor' positions which were sponsored by pharmaceutical companies. Progression in these roles led towards more typical PSR positions, but both reported retaining their passion for patient care from their nursing backgrounds. |
| PSR 6 | This PSR began their career as a pharmacist and was recruited by a pharmaceutical company whilst working as a pharmacist in a hospital. |
| PSR 7 | See PSR 5. |
| PSR 8 | This PSR entered the pharmaceutical industry after a short career in another industry. |
| Healthcare Economist 1 | This informant is a researcher that I found via Disclosure UK. They have consulted for |

| | pharmaceutical companies and conducted pharma- |
|------------------|--|
| | funded research on the disease burden of |
| Neuroscientist 1 | depression. This informant is also a researcher I found via |
| | Disclosure UK. |
| Pharmacist 1 | Pharmacists were the most diverse group of |
| | informants I spoke to. Pharmacist 1 is one of the |
| | involved in making very high-level decisions relating |
| | to the use of medicines by the NHS. |
| Pharmacist 2 | |
| Pharmacist 3 | |
| Pharmacist 4 | |
| Pharmacist 5 | |
| Pharmacist 6 | |
| Pharmacist 7 | |
| Pharmacist 8 | |
| Psychiatrist 1 | |
| Psychiatrist 2 | |
| Psychiatrist 3 | |
| Psychiatrist 4 | |
| Psychiatrist 5 | |
| Psychiatrist 6 | |
| Psychiatrist 7 | |
| Psychiatrist 8 | |
| Psychiatrist 9 | |
| Psychiatrist 10 | |
| Psychologist 1 | |
| Psychologist 2 | |
| Psychologist 3 | |
| GP 1 | |
| GP 2 | |
| GP 3 | |
| GP 4 | |
| GP 5 | |

Appendix B: Consent form

Rachel Williams <u>WilliamsRD3@Cardiff.ac.uk</u> +44 7845322816

Consent Form

An Investigation into the Marketing of Antidepressants

I understand that my participation in this project will involve taking part in a 60 minute interview on the marketing of antidepressants and the wider context of depression and its treatment.

I understand that the interview will be recorded and transcribed at a later date.

I understand that participation in this study is entirely voluntary and that I can withdraw from the study at any time without giving a reason.

I understand that I am free to ask any questions at any time. If for any reason I have second thoughts about my participation in this project, I am free to withdraw or discuss my concerns with Dr Michael Marinetto (marinettom@cardiff.ac.uk).

I understand that the information provided by me will be held confidentially and securely, such that only the researcher can trace this information back to me individually. The information will be retained for up to a year after the project's completion and will then be anonymised, deleted or destroyed. I understand that if I withdraw my consent I can ask for the information I have provided to be anonymised/deleted/destroyed in accordance with the Data Protection Act 1998.

I, ______(NAME) consent to participate in the study conducted by Rachel Williams (williamsrd3@cardiff.ac.uk) PhD Student of Cardiff Business School, Cardiff University, under the supervision of Dr Michael Marinetto.

Signed:

Date:

Rachel Williams <u>WilliamsRD3@Cardiff.ac.uk</u> +44 7845322816

Participant Information Sheet

An Investigation into the Marketing of Antidepressants

What is the purpose of this study?

This research aims to investigate how antidepressants are marketed and have been marketed over time. Furthermore, this study will explore the issues pertaining to the marketing of antidepressants. Part of this research will involve interviewing people from patient charities about their experiences and opinions of antidepressant marketing, in addition to the wider context of depression and its treatment

What does participation involve?

Participation in this research will involve at least one interview lasting either approximately 60-90 minutes if face-to-face, or 30-45 minutes over the telephone. The interview will be semi-structured, with the topics and questions depending on the role of the person being interviewed. Over the course of the interview, participants are not required to answer all questions, and can stop the interview at any time.

The interview will be recorded using a voice recorder and transcribed at a later date. All data will automatically be anonymised, however, if preferred, respondents can opt to be identified in any published works.

Participants will also be given the option of consenting to be contacted again after the initial interview should further questions arise during the research process. Consent for all aspects of this research can be withdrawn at any time.

What will happen to the findings?

The research findings will be published in a doctoral dissertation, and potentially academic articles. It is likely the findings will also inform further research into the topic.

Contact details

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Rachel Williams

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<u>Supervisors</u>

Dr Michael Marinetto Email: <u>MarinettoM@Cardiff.ac.uk</u>

Dr Kate Daunt Email: <u>DauntK@Cardiff.ac.uk</u>

Appendix D: Ethical Approval Form

| ETHICS 2 | | | Business | Ysgo Fusnes |
|---|---|---|--|--|
| FULL ETHI | CAL APPROV | VAL FORM | Cardiff University | Caerayac Prifysgol Caerdydd |
| (For guidanc | e on how to comp | lete this form, please see Le | arning Central – CARBS RE | SEARCH ETHICS) |
| If your research National Resear | n will involve pati- rch Ethics Service | ents or patient data in the N . Online applications are av | HS then you should secure a ailable on <u>http://www.nres.np</u> | pproval from the N bsa.nhs.uk/applicant |
| Name of Lead F | Researcher : Ra | chel Williams | | |
| School: | Cardiff Bus | siness School | | |
| Email: | WilliamsR | D3@Cardiff.ac.uk | Reso | |
| Names of other | Researchers: | N/A | Cardiff Business | APPROVED |
| Email addresses | of other Research | hers: N/A | Univer | School Sity |
| Title of Project: | | | | |
| An Investigatio | on into the Ethic | al Status of Markating A | ntidonananata | |
| | | a status of Marketing A | nudepressants | |
| Aims and Object To iden pharma To unde adopted To expl (includin profile c And to a | tives of the Resear tify which meth accutical corpor- erstand and and d. ore the attitude: ng: the pharma commentators o ultimately consi- any sources of fund | rch Project: ods are used, and have ations. alyse the broader contex s of various stakeholders ceutical industry, medica in the pharmaceutical ind der and reflect upon the ing for this project: | been used to market antic t within which these meth t towards antidepressant l practitioners, patient gro lustry such as authors an ethical status of antidepre | depressants by ods have been marketing ups and high d journalists) ssant marketing. |
| lease indicate ar | -y sources of fund | ing for this project. | | |
| Please indicate ar | Business School | | | |
| Please indicate ar | Business School | | | |
| Please indicate and ESRC and Cardiff | Business School e methodology | to be applied in the proj | ect | |

pharmaceutical industry.

If participants consent to have the interview recorded, interviews will be transcribed and coded based on the themes and attitudes presented. Should the participant not consent, comprehensive notes will be taken and coded similarly. If access is granted to shadow pharmaceutical industry employees, field notes will be taken and coded thematically.

Documents will be also collected and analysed throughout the research process. Such documents may include marketing materials, archival materials, letters, emails and newsletters. As with the other information gathering techniques, documents will be coded and analysed based on themes and attitudes presented. Should prescription data be available for analysis, it will be requested that such data is anonymised before being accessed for research purposes. If such information is available, it will be analysed using basic quantitative techniques such as regression analysis.

2. Describe the participant sample who will be contacted for this Research Project. You need to consider the number of participants, their age, gender, recruitment methods and exclusion/inclusion criteria

Participants will be selected using the 'snowball' method. A few participants have already been selected, having participated in previous research, these participants will identify other individuals to interview, who in turn will identify others. Additionally, potential interviewees will be identified through the investigative process. For example, individuals named in documents related to antidepressant marketing.

It is anticipated that the participants will be of mixed age and gender, however all will be legal adults. Participants will be included in the study on the basis that they have some experience of antidepressant marketing, either as a medical professional, a pharmaceutical industry employee, or as an industry commentator. Participants will be excluded if they have no experience of knowledge of the proposed subject matter or if they choose not to consent.

3. Describe the method by which you intend to gain consent from participants.

All participants will be given information about the research prior to their participation, and will be asked for consent on the day of the first interview. There will be an additional option for anonymity of their identity. It is expected that pharmaceutical industry employees and healthcare professionals will wish to remain anonymous, however based on previous research it is anticipated that some individuals, such has high profile critics, may prefer to be identified.

4. Please make a clear and concise statement of the ethical considerations raised by the project and how you intend to deal with them throughout the duration of the project (please use additional sheets where necessary)

As the research involves NHS employees it was discussed with the university research governance officer, and the R&D Facilitator for the local NHS health board whether NHS ethical approval was required. Ultimately it was decided that as the participants will not be recruited via NHS institutions NHS approval is not required.

To become informed of the potential ethical issues encountered when conducting research on a medical topic I have attended an introductory course on Good Clinical Practice, accredited by the NHS. The certificate from which will be valid for two years, after which I will attend the course again to stay informed. It is anticipated that retaining a link with the NHS research governance network in this way will improve contextual understanding decision-making if and when ethical questions arise during the course of the project.

Healthcare participants will not be asked directly about patients. However there is a chance participant's may refer to a patient or patients in their responses. All respondents will be reminded not to discuss specific or identifiable patient information. Should identifiable patient information be disclosed, recording of the interview will be immediately stopped, the participant will be reminded that such information cannot be discussed, and the interview will come to a gradual close, with one to two more neutral questions asked so as not to offend the respondent. The recording of the interview will be kept, with the section involving the disclosure destroyed.

Please complete the following in relation to your research project:

| | | Yes | No | n/a |
|-----|---|-----|-------------|-----|
| (a) | Will you describe the main details of the research process to participants in advance, so that they are informed about what to expect? | | | |
| (b) | Will you tell participants that their participation is voluntary? | | | |
| (c) | Will you obtain written consent for participation? | | \boxtimes | |
| (d) | Will you tell participants that they may withdraw from the research at any time and for any reason? | | | |
| (e) | If you are using a questionnaire, will you give participants the option of omitting questions they do not want to answer? | | | |
| (f) | Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs? | | | |
| (g) | Will you offer to send participants findings from the research (e.g. copies of publications arising from the research)? | | | |

PLEASE NOTE:

If you have ticked No to any of 5(a) to 5(g), please give an explanation on a separate sheet.

(Note: N/A = not applicable)

There is an obligation on the principal researcher/student to bring to the attention of Cardiff Business School Ethics Committee any issues with ethical implications not clearly covered by the above checklist.

| Signed: | Co Busiles OPPRO |
|--------------------------------|--------------------|
| (Principal Researcher/Student) | ardise ineo Com VI |
| Print Name: | Divis Southitte |
| | Orsis noor |
| Date: | |

SUPERVISOR'S DECLARATION (Student researchers only): As the supervisor for this student project I confirm that I believe that all research ethical issues have been dealt with in accordance with University policy and the research ethics guidelines of the relevant professional organisation.

| Stoned. | |
|----------|--|
| orginou. | |

Print Name:

Date:

TWO copies of this form (and attachments) MUST BE OFFICIALLY STAMPED by Ms Lainey Clayton, Room F43, Cardiff Business School

STATEMENT OF ETHICAL APPROVAL

This project has been considered using agreed School procedures and is now approved.

APPLICATION APPROVED Research Eithics Composition Cardiff Business Committee Cardiff University Official stamp of approval of the School Research Ethics Committee:

Date: Morch 2015

Attachment 1: Further Explanation for Section Five

5(c) – Respondents will be given information sheets about the research in advance and given some time to decide if they want to take part in the research, prior to being interviewed. A copy of the consent form will be included in the information pack. If a participant agrees to be interviewed in person, they will be asked to sign a consent form at the first interview.

For respondents who are not available to be interviewed in person, phone or video chat interviews will take place. For these interviews, consent to record the conversation will be prerequisite. This will be explained to respondents in the information sheet and also reiterated over email prior to making the phone call. Verbal consent will then obtained and recorded verbally prior to the interview commencing. Verbal consent will be obtained by reading the consent form aloud, and getting a definite 'yes' from respondents prior to starting the main portion of the interview.

For respondents who are unable to meet in person, but who also do not feel comfortable with being recorded, an email conversation option will available. For these respondents, it will requested that they include a statement acknowledging they give their informed consent at the start of the first email before responding to any questions.

5(f) – Participants will be given the default option of anonymity. There will, however, also be an option for participants to be identified in the findings. The option for identification is being offered based on previous research, during which it was discovered that some high profile industry commentators would prefer to have their identifies disclosed.

Participants who do not decide to disclose their identity will have their data treated will full confidentiality and will not be identifiable in any published research. For participants who choose to disclose their identity they will be told that they can change their decision regarding this at any time.



Attachment 2: NHS Correspondence

From: Lee Hathaway (Cardiff and Vale UHB - Research & Development) [mailto:Lee.Hathaway@wales.nhs.uk] Sent: 11 February 2015 11:47 To: Rachel Williams Cc: Helen Falconer Subject: RE: R&D Queries

Dear Rachel,

I can confirm that, if you are not recruiting via Cardiff and Vale UHB, then you will not need R&D approval from Cardiff and Vale UHB.

Regards Lee

Mrs Lee Hathaway **R&D** Facilitator R&D Office, 2nd Floor TB2 University Hospital of Wales Heath Park Cardiff **CF14 4XW** Tel. 029 2074 2028 Fax. 029 2074 5311

Lee.hathaway@wales.nhs.uk

From: Rachel Williams [mailto:WilliamsRD3@cardiff.ac.uk] Sent: 10 February 2015 08:58 To: Lee Hathaway (Cardiff and Vale UHB - Research & Development) Subject: Fw: R&D Queries

Hi Lee,

Helen has informed me that if I am not recruiting staff via NHS institutions then it is unlikely I will toh Ethics Committee ASSET OF FOUNDS CONTINUES CONTINUES CONTINUES SCON

Cardiff Univers

Rachel

From: Helen Falconer Sent: 02 February 2015 14:11 To: Rachel Williams Subject: RE: R&D Queries

Hi Rachel,

If you are not approaching and recruiting staff through their place of work, then your study is unlikely to require NHS R&D approval, but it's worth confirming this with the R&D office. You may require authorisation from professional bodies/charities etc., if you decide to approach staff through other routes. If this changes at any point, then please let me know as this might affect the approvals you require.

If you are only involving members of staff, then you will need ethical approval from your School Ethics Committee only (not NHS ethical approval).

I hope this helps, please let me know if you have any questions.

Best wishes Helen

Helen Falconer Research Governance Officer

Research and Innovation Services Cardiff University 7th Floor, McKenzie House 30-36 Newport Road Cardiff CF24 0DE

Tel: +44(0)29 2087 9277 Email: <u>falconerhe@cardiff.ac.uk</u>

Swyddog Llywodraethu Ymchwil

Gwasanaethau Ymchwil ac Arloesi, Prifysgol Caerdydd 7^{fed} Llawr, Tŷ McKenzie 30-36 Heol Casnewydd Caerdydd CF24 0DE

Ffôn: +44(0)29 2087 9277 E-bost: <u>falconerhe@caerdyyd.ac.uk</u>



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From: Rachel Williams Sent: 29 January 2015 14:36 To: Helen Falconer Subject: RE: R&D Queries

APPI ICATION Research Strics APPROVED Cerdiff Elisiness Committee Cardiff University University

Hi Helen,

Thanks so much for getting back to me. I won't be recruiting staff through their place of work. I have contact with one GP already as she is my supervisors neighbour, and then I will be using a snowball sampling method. I also may be contacting people who are identified in archival materials. If I don't have to do NHS R&D approval are there any other applications I'd need to do other than my school ethical (approval?

Thanks,

Rachel

From: Helen Falconer Sent: 29 January 2015 09:29 To: Rachel Williams Cc: Lee Hathaway (Cardiff and Vale UHB - Research & Development) Subject: RE: R&D Queries

Dear Rachel,

I agree that your study is more appropriately classified as research.

Will you be recruiting the NHS practitioners through their place of work, or via another route (e.g. conferences, unions, professional networks?) If you're not accessing staff through their place of work and during working hours, then you may not require NHS R&D approval (and therefore wouldn't necessarily need the IRAS form). As your study doesn't involve patients, then you will need to seek ethical approval via the University system (through your School Ethics Committee), rather than the NHS Research Ethics Service.

If you would find it easier, you can transfer the IRAS form to me and let me know which bits you're stuck on, I can then have a look.

Best wishes Helen

Helen Falconer **Research Governance Officer**

Research and Innovation Services Cardiff University 7th Floor, McKenzie House 30-36 Newport Road Cardiff CF24 ODE

Tel: +44(0)29 2087 9277 Email: falconerhe@cardiff.ac.uk

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Ffôn: +44(0)29 2087 9277 E-bost: falconerhe@caerdyyd.ac.uk APPLICATION APPROVED

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Attachment 3: Consent Form

Rachel Williams <u>WilliamsRD3@Cardiff.ac.uk</u> +44 7845322816

Consent Form

An Investigation into the Marketing of Antidepressants

I understand that my participation in this project will involve taking part an interview of approximately 60-90 minutes discussing the marketing of antidepressants. I understand that the interview will be audio recorded and transcribed at a later date.

I understand that participation in this study is entirely voluntary and that I can withdraw from the study at any time without giving a reason.

I understand that I am free to ask any questions at any time. If for any reason I have second thoughts about my participation in this project, I am free to withdraw or discuss my concerns with Dr Michael Marinetto (marinettom@cardiff.ac.uk).

I understand that the information provided by me will be held confidentially and securely, such that only the researcher can trace this information back to me individually. The information will be retained for up to a year after the project's completion and will then be anonymised, deleted or destroyed. I understand that if I withdraw my consent I can ask for the information I have provided to be anonymised/deleted/destroyed in accordance with the Data Protection Act 1998.

Please tick here if you are happy to be connected again for further interviews p

Please tick here if you would like to forgo anonymity and be identified in any research publications \square

I, ________(NAME) consent to participate in the study conducted by Rachel Williams (williamsrd3@cardiff.ac.uk) PhD Student of Cardiff Business School, Cardiff University, under the supervision of Dr Michael Marinetto.

Signed:

Date:

Attachment 4: Participant Information Sheet

Participant Information Sheet

An Investigation into the Marketing of Antidepressants

What is the purpose of this study?

This research aims to investigate how antidepressants are marketed and have been marketed over time. Furthermore this study will explore the issues surrounding antidepressant marketing. Part of this research will involve interviewing healthcare professionals on their experiences and opinions of antidepressant marketing.

What does participation involve?

Participation in this research will involve at least one interview, either in person or over the telephone lasting approximately 60-90 minutes. The interview will semi structured, covering topics such as opinions and experiences of antidepressant marketing. During the course of the interview, participants are not required to answer all questions, and can stop the interview at any time.

The interview will be recorded using a voice recorder and transcribed at a later date. All data will automatically be anonymised, however, if preferred, respondents can opt to be identified in any published works.

Participants will also be given the option of consenting to be contacted again after the initial interview should further questions arise during the research process. Consent for all aspects of this research can be withdrawn at any time.

What will happen to the findings?

The research findings will be published in a doctoral dissertation, and potentially academic articles. It is likely the findings will also inform further research into the topic.

Contact details

Principal Investigator:

Rachel Williams Telephone: +44 7845322816 Email: WilliamsRD3@Cardiff.ac.uk

Supervisors

1

Dr Michael Marinetto Email: MarinettoM@Cardiff.ac.uk

Dr Carl Cederström Email: cce@sbs.su.se

Dr Kate Daunt Email: DauntK@Cardiff.ac.uk

ETHICS 2

Search Ethics Committee