CASE STUDY 7

A Case of Critical Thinking: Marketing Strategies Used to Promote Licensed Drugs

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INTRODUCTION

The UK government has stressed the need to question and challenge the actions of drug companies and the effect they may have on patients. A report by the House of Commons (HoC) Health Select Committee on *The Influence of the Pharmaceutical Industry* noted that it was important 'to examine critically the industry's impact on health to guard against excessive and damaging dependencies' (HoC 2005, p. 97). Given 'profit-maximisation' is drug companies' main purpose while patients strive for the 'optimisation of drugs' benefit-risk ratios' (Abraham 2008, p. 869), this called for a case of critical thinking.

PROBLEM DEFINITION

Regulatory failures are of great concern to public health whether inefficiencies in pharmaceutical regulation are attributed to corporate bias (Middlemas, 1979, Abraham, 2008; Lewis and Abraham, 2001) or regulatory capture (Abraham, 2008). If patients take licensed drugs that, for whatever reason should not be on the market, death may be the end result.

This is obviously a problem. But who should be accountable when health regulatory systems fail to protect patients or when drug companies use illegal or unethical marketing practices to promote their products and are not sufficiently sanctioned? If regulators are to fulfil their mission of protecting and promoting public health, then they have a duty to act as dependable decision-making bodies. However, sometimes this trust is misplaced (Davies, 2007; Farrar, 2000; McGoey, and Jackson, 2009; Smith, 2005).

If regulators cannot be trusted to protect public health, then perhaps patients should place their trust in the doctors who take an oath to put their interests first? But here again, the academic literature proves it unwise to place blind faith in such authority. Indeed, research indicates that medical practitioners are partly responsible for the 'medicalisation of society' and its dependency on pharmaceuticals (Conrad, 2007; Illich, 1975). There is also evidence that physicians' behaviours are influenced by drug company promotions (Goodman, 2001) and that many doctors are 'on the take' (Kassirer, 2005).

Furthermore, pharmaceutical research departments in academic institutions have been accused of promoting 'science in the private interest' (Krimsky, 2003), while esteemed 'independent' scientists working for universities, and on the pharmaceutical industry's payroll, have been the source of much controversy (McHenry, 2010).

Elsewhere, the media has been accused of scaremongering and propagating health scandals (Coombes, 2009). There are documented examples of public relations (PR) practitioners, lobbyists and research institutions being hired by drug companies to influence policymaking (Abraham, 2002; Burton and Rowell, 2003; Miller and de Andrade, 2010) and patient advocacy groups (PAGs) and charities increasingly collaborating with industry (Moynihan and Cassels, 2005).

Clearly, patients do not immediately know who to trust when licensed drugs are illegally or unethically marketed. Neither do they know who must be held responsible when things go wrong.

The following case explores the importance of independent critical thought in the context of public health.

STAKEHOLDER ANALYSIS

The main identified stakeholders[1] from a review of the literature are:

- patient advocacy groups (PAGs);
- medical communication companies/medical education firms;
- academics (and educational institutions);
- regulators,
- medical practitioners;
- PR firms;
- the media; and
- lobbyists

AIMS AND OBJECTIVES

This case study identifies which of these stakeholders collaborated during the promotion of a selected licensed drug. It highlights some of the strategies used to promote the drug off-label[2] due to these affiliations, and helps to determine who may be accountable for ineffective pharmaceutical regulation. Finally, it considers why this is important for critical marketers.

RESEARCH AND EVALUATION

A documentary analysis was conducted of internal industry documents pertaining to olanzapine (or Zyprexa), which became publicly available during legal proceedings in the US. Eli Lilly's atypical antipsychotic agent was licensed in the UK and the US in 1996 to treat schizophrenia, bipolar I disorder and agitation associated with these conditions (Lader, 1999; Spielmans, 2009; Spielmans, and Parry, 2010; United States Department of Justice (USDJ), 2009).

From September 1999 until at least November 2003, its manufacturer was accused of promoting the drug off-label for the treatment of agitation, aggression, hostility, dementia, Alzheimer's dementia, depression and generalized sleep disorder (Berenson, 2006; Goldstein, 2007; USDJ, 2009). In 2009, Lilly conceded that it had promoted the drug's use for the treatment of dementia and 'plead[ed] guilty to a misdemeanor criminal charge of misbranding' (Spielmans, 2009; USDJ, 2009).

Olanzapine was also linked to side effects including weight gain, the onset of diabetes mellitus and hyperglycemia, which manufacturer's neglected to inform patients (Berenson 2006; Guo et al. 2006; Guo et al. 2007; Bogenschutz and Nurnberg 2004; Robinson et al. 2006).

In excess of 300 internal documents were reviewed for a larger study (from which selected findings are presented here). These documents entered the public domain in 2006, when they were leaked to a *New York Times* reporter and articles subsequently published. US court proceedings ruled in favour of allowing original litigation documents to be disseminated on various websites and the entire dataset is available on *Furious Seasons*

[1] Isolated criticisms of the pharmaceutical industry arising from its affiliations with these stakeholders have been consolidated as a model of intra-elite communication in pharmaceutical regulation called *Pharmaffiliation*. By focusing on the nature of relationships between these affiliated stakeholders, the model facilitates an understanding of why pharmaceutical regulation may be ineffective (de Andrade, forthcoming).

[2] This is when a pharmaceutical product is prescribed for an unapproved indication.

(www.furiousseasons.com). All documents, dated from 2000 to 2005, were reviewed and analysed thematically, according to relevant stakeholders. They have also been used in the academic literature to illustrate how olanzapine was marketed in primary care settings in the US, and how there is a trend towards 'marketing-based medicine' (Spielmans, 2009; Spielmans and Parry, 2010). Quotes presented in the case study have been drawn from internal industry documents.

FORMULATION OF STRATEGY

A series of promotional strategies were implemented among the following groups:

- medics
- academics and medical education firms
- patient advocacy groups
- PR firms
- regulators

1. Promotional Strategies with Medical Practitioners

Following a lengthy study by the US brand team, the drug company decided to 'actively promote Zyprexa to selected primary care prescriber [PCP] targets' as the 'potential in this arena' was 'virtually untapped' (Eli Lilly, 2000).

Specific messages were developed, market research conducted and a training calendar created to direct the strategy to PCP targets. The project additionally involved a 'communications plan', 'customer targeting and direct-to-physician initiatives' and 'additional pre-launch activities', such as 'sales force integration' and 'sales support items' (Eli Lilly, 2000).

The brand team 'focused on two key points of emphasis': 'peer-to-peer activity and competitive differentiation'. To achieve this, Lilly 'completed the second of two speaker training programs' and 'unleashed more than 130 psychs [psychiatrists] and PCPs' who were 'chomping at the bit to help you [sales representatives] sell Zyprexa' (Eli Lilly 2001b).

Lilly also outlined its intention to create effective PR strategies to disseminate key messages related to diabetes and weight gain. The 'Zyprexa Infonet' was set up with online links to the latest product information, positioning statements, strategies, tactics and best practices. Tactical resources made available to company representatives included medical letters, standby statements, sales force verbatim, sales force training materials, publications and studies and slide sets and posters (Eli Lilly, 2002a).

2. Promotional Strategies with Academics and Medical Education Firms

Internal emails indicated that some Lilly representatives felt uneasy about the drug's associated link to weight gain and diabetes. A poster presentation at a conference, for example, caused much distress as it assessed the risk of antipsychotic induced diabetes among schizophrenics and concluded that olanzapine was among the drugs 'associated with a significant risk of developing type 2 diabetes when compared to typical antipsychotics'. It was brought up by a Lilly representative as it would almost undoubtedly be published and 'raise noise around diabetes and olanzapine' (Eli Lilly, 2002d).

Attention turned to how the company could minimise the impact of the manuscript both locally and globally. Representatives were asked to consider where the paper would be published and if it would be possible to halt or postpone publication. It was suggested that the latter would be

problematic unless a company scientist could demonstrate that the entire methodology was defective. The notion that it may be possible to influence the author was raised, even though the danger of this was acknowledged as it was deemed an unethical action. Similarly, representatives were asked to consider whether it may be possible to shape the decisions of those on the selected journal's editorial board and if high-ranking referees should be contacted and made aware of methodological restrictions (Eli Lilly, 2002d).

It was proposed that Lilly immediately start penning a 'landmark' paper, which would be published in a high-profile journal and written by a 'credible' individual who was sympathetic towards the company's position. One representative asked about the company's collaborations with medical education firms and whether these stakeholders could rapidly step in to assist (Eli Lilly, 2002e).

The drug company decided to identify an external 'Consultant Panel' to examine the issue of hyperglycemia, and hire someone who would appear to be 'independent' (Eli Lilly, 2002b). A consultant, who was familiar with the data, was considered; an academic, who served on the Lilly board was a doubtful candidate as he was 'too close'; and a specialist employed by another pharmaceutical company was not supported. One Lilly representative reiterated the importance of not selecting a chairperson with a 'pre-existing' and 'longstanding relationship' with the company (Eli Lilly 2002b).

3. Promotional Strategies with Patient Advocacy Groups

Lilly built strong relationships with influential patient advocacy groups such as the American Diabetes Association (ADA), a PAG that 'aims to prevent and cure diabetes and to improve the lives of all people affected by diabetes' (ADA, 2011). In 2004, the group announced that there was a link between Zyprexa and diabetes (ADA, 2004).

Internal email exchanges illustrate how the drug company conducted an 'after action review' of the ADA's recommendation. The review process was considered to be extremely advantageous as it could be applied 'to the broader long term Neuroscience influence agenda' (Eli Lilly, 2004). A Lilly representative stated that the company was aware of 'ADA influence' and therefore 'should have had a greater influence early on before it was a done deal'. This had occurred as the drug company had 'underestimated the players' and 'didn't really understand [the] role & approach [the] competition would take'. Consequently, it had 'inadequately influenced key players on decision [making]'; made a presentation to America's health regulator, the Food and Drug Administration, which 'was not as strong as it could have been to influence [the] group (particularly [in] the response to the weight gain question); and responded in the 'press' 'at a point [which was] too late to fundamentally influence the outcome' (Eli Lilly, 2004).

4. Promotional Strategies with PR Firms

A Zyprexa management team was set up with representatives from the company's medical, regulatory, corporate affairs, health outcomes and marketing divisions. Two representatives from the PR firm, Cohn & Wolfe, were also enlisted (Eli Lilly, 2002a).

5. Promotional Strategies with Regulators

To manage its relations with regulators, the company planned 'pre-emptive actions' to manage 'critical external issues' such as 'regulatory environment uncertainties'. It recognised the importance of building 'flexibility' into its business strategy 'to allow for fulfilment of unexpected requirements from regulatory authorities' and 'to shape regulatory decisions and requirements' (Eli Lilly, 2001a).

DISCUSSION

The case shows that marketing olanzapine for approved and off-label uses was a priority for Eli Lilly and the product team vigorously pursued this objective by devising strategies to promote the drug. This they did through collaboration with several stakeholders, including medical practitioners, regulators, medical communication companies, PAGs and PR firms.

Building and maintaining strong relationships with respected academics, key opinion leaders, PAGs and medical practitioners was a priority, as was working with PR firms to disseminate positive messages about the product and adapting strategies to shape regulation.

This case illustrates the necessity of understanding that marketing strategies are implemented with other players in the pharma-sphere – the stakeholder network comprised of individuals or groups collaborating with the pharmaceutical industry during licensed product promotion – and that these stakeholders help shape and define the messages disseminated to the public through the media and other channels. In this way, they consciously or unconsciously facilitate the industry's pursuit for profit. Relations in the stakeholder network also make it difficult to apportion blame to specific stakeholders. By exploring the nature of the relationships between elite stakeholders who collaborate with the pharmaceutical industry during the promotion of licensed drugs, it may therefore possible to understand how pharmaceutical regulation is ineffective due to systemic problems (de Andrade, forthcoming).

Undoubtedly, several drugs produced by the pharmaceutical industry are beneficial to society. But, when licensed drugs are misbranded and marketing strategies used to promote products that may be harmful to patients, the consequences of an inefficient pharmaceutical regulatory system become all the more apparent. It is therefore imperative for consumers to be aware of the 'dark side of marketing' in the public health arena and think critically about the ways in which other stakeholders may be inadvertently or deliberately facilitating corporate motivations.

CASE STUDY QUESTIONS

1. Which stakeholders collaborate with the pharmaceutical industry during the promotion of licensed drugs?

2. How may drug companies attempt to stop competitors from promoting their products?

3. Which important stakeholders are not always a part of pharmaceutical regulatory processes? Why do you think this is the case?

4. How may transnational drug companies be subsuming and undermining regulatory systems and consequently turning them into a marketing enterprise?

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