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Patient involvement in drug licensing: A case study

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ABSTRACT

Embodied health movements work on the boundary between lay and expert knowledge. Consumer groups, depending on their goals, may increase or decrease pharmaceuticalization. This paper reports a small case study about the retrospective evaluation of a specific second line treatment for type 2 diabetes by an existing patient involvement group. The group is part of a research collaboration between academia and the health service in England, and shares some characteristics of embodied health movements. We used the case study to explore whether an institutionally funded non activist patient group can make a more balanced contribution to drug licensing decisions than that made by either access-oriented or injury-oriented consumer groups, without being co-opted by an institutional agenda. The questions we wished to address were how this group evaluated existing mechanisms for licensing drugs; how they balanced scientific and lay knowledge; how they made their decisions; and how they viewed their experiences as panel members. The five panel members were interviewed before and after the panel discussion in July 2013. They were critical of current licensing processes, and used their own embodied experiences of medicines to evaluate expert knowledge. Their decisions on the panel were informed either by a balancing of benefits and harms, or by trust in experts. The case study suggests that such a group may have the potential both to balance the pro-pharmaceuticalization impact of access-oriented groups and to influence forms of pharmaceutical governance.

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1. Introduction

Health professionals, by the nature of their training and work, necessarily belong to social groups. The same cannot be said for patients who may have little contact with others in the same situation, although the internet is changing this. However there is an increasing range of social groups whose members share aspects of patienthood, such as self-help groups and disease-based campaigning groups. Perhaps the most well-known are those patient groups lobbying for access to new drugs, whose activities are often reported in the media. Such groups can accelerate regulatory approval (Carpenter, 2004), thus contributing to processes of pharmaceuticalization (Williams et al., 2011). In his work on the Food and Drug Administration (FDA) Drug Review process, Carpenter (2004) identified more than 3000 disease and patient advocacy groups in the US representing various medical conditions for which new drug applications had been submitted. Abraham has defined pharmaceuticalization 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' (Abraham, 2010, p. 604). He considered the role of consumerism as a driver of pharmaceuticalization and noted that there are two types of active consumerism: one based on injury-oriented adversity to the pharmaceutical-industrial complex, and one based on access-oriented collaboration with it. The ability of such groups to achieve their ends depends on whether they support or oppose the interests of the pharmaceutical industry. Abraham concluded that although both types of group do influence processes of pharmaceuticalization, the pro-pharmaceuticalization consequences of access-oriented consumerism tend to outweigh the de-pharmaceuticalization effects of injury-oriented adversarial consumerism.

HIV/AIDS activists were possibly the earliest of the access-oriented groups to achieve success and public notoriety in influencing drug regulatory and licensing decisions as well as the actual conduct of scientific research (Epstein, 1996). Epstein (1995)

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identified four tactics used by HIV/AIDS activists to achieve their goals: acquiring cultural competence in the language of biomedicine; establishing themselves as representatives of potential research subjects; yoking together methodological and moral arguments; and taking sides in pre existing debates, notably about pragmatic trials. These tactics were leveraged by highly dramatic publicity stunts which captured media attention. At first activists focused attention on the regulatory processes, putting pressure on the FDA to speed up the approval of new drugs; as they learnt more about what counted as 'good science', they later contributed to debates about the conduct of randomised clinical trials (RCTs). Activists advocated the use of surrogate outcome measures in clinical trials; they contested norms about what constituted suitable trial populations and placebo controlled trials; and took part in debates about pragmatic and fastidious trials (Epstein, 1996). They transformed scientific practices by creating new pathways for the dissemination of scientific information; sitting on funding bodies to determine which studies were funded; influencing the redefinition of AIDS to include HIV-related conditions affecting women; contributing to new regulatory and interpretive mechanisms by the FDA and NIH; and influencing arguments about how clinical trials should be conducted (Epstein, 1995). HIV/AIDS activists were mostly self-taught, although a few were already members of the scientific community. As time went on, the treatment activists became detached from the communities they claimed to represent, leading to a division within the HIV/AIDS movement between highly knowledgeable autodidact 'lay expert' activists and the 'lay lay' activists.

Hess (2004) used the term 'medical modernisation' to characterise the ways in which modern scientific medicine responds to challenges to its epistemic authority from social movements and from complementary and alternative medicine. He argued that under conditions of medical modernisation, the distinction between lay (or alternative) knowledge and scientific knowledge, upon which the epistemic authority of medicine rested, is submerged in a more complex field of competing scientific networks and research programmes. This includes an emerging system of the 'public shaping of science' in which social movements have greater agency, and there is greater recognition of the legitimacy of that agency. Indirect public shaping of science takes the form of engagement with the policy process or funding decisions, while direct public shaping occurs when activists help to develop new research programmes to address their own goals rather than those of the dominant research programmes. Hess noted that further work was needed to understand the co-optation process of both patient advocacy group and CAM practitioners.

In the context of increasing scientization of decision making in which the public is excluded from many important policy debates (Brown and Zavestoski, 2004), the work of Brown et al. (2004) on health social movements explored their potential for challenging medical policy and practice. Brown et al. distinguished between health access movements, constituency based health movements and embodied health movements, while acknowledging that the boundaries between these types are fluid. They defined embodied health movements (EHMs) as 'organised efforts to challenge knowledge and practice concerning the aetiology, treatment, and prevention of disease' (Brown et al., 2004, p. 54). Members of EHMs have a politicised collective identity born of a collective illness identity which turns a personal trouble into a social problem; a sense of grievance is central to the formation of EHMs. Since they depend on challenging medical and scientific knowledge and practice, EHMs are constantly engaged in boundary work and may be characterised as boundary movements in four ways: they attempt to redraw the lines demarcating science from non science; they blur boundaries between experts and lay people; they transcend the usual limits of social movement activity; and they use boundary objects, such as scientific devices which are also used for political purposes. Members of these movements (for example, breast cancer activists) challenge science on the basis of their own intimate knowledge of their own bodies, in other words, their experiential knowledge. Members of embodied health movements may collaborate with scientists as well as challenging them, and the Silent Spring Institute in the US is an example of an institutionalised citizen-science alliance. In such alliances, scientists come to value the contributions of lay people and in the process, scientific norms are changed. In the UK, patient and public involvement in research has had some impact on the way in which health research is conducted (Staley, 2009). Brown et al. referred to the moral credibility bestowed by members' lived experience of the disease, which is unavailable to scientists. As members of embodied health movements learn about the science relevant to their conditions, the boundary between experts and lay people become blurred. Lay people may become more knowledgeable through the internet and reading scientific papers, increasingly available via open access publishing, while scientists may become advocates for the movements they collaborate with. Some groups teach science courses for activists, for example the Project LEAD (leadership, education and advocacy development) offered by the National Breast Cancer Coalition (Dickersin et al., 2001) and French AIDS associations (Barbot, 2006).

A central question for those studying health social movements is that of conflict of interest, particularly for access-oriented groups (Hess, 2004). Unsurprisingly, many of them receive financial support from the pharmaceutical industry, leading to conflicts of interest (Hemminki et al., 2010). In a study of pharmaceutical sponsorship of health consumer groups in the UK, Jones (2008) concluded that although industry did not seem to have captured the policy agenda of these groups, their lack of disclosure about funding sources might undermine the willingness of policy makers to see them as legitimate spokespeople for patients and carers.

Most of the social movements discussed above have been 'bottom up' movements driven by collective and politicised identities, with clear goals of their own in relation to treatment access, redress for injury, or better health care. Given the epistemic achievements of many social movements, the question arises whether broader public participation in pharmaceutical policy might have a wider contribution to make, beyond issues of access and redress. In particular, public participation is surely relevant in situations of long term treatments for chronic illnesses, in which patients are expected to take drugs for the rest of their lives. If those seeking access tend to focus on efficacy, and those seeking redress from injury focus on safety, what about patients who are not activists? Licensing decisions for such drugs do not currently take the views of end users into account (Eichler et al., 2012; Britten, 2008). In this paper, we wish to use a small case study to explore the question of whether a separately funded non activist patient group can make a more balanced contribution than that made by either access-oriented or injury-oriented groups, without being co-opted by an institutional agenda. By this we mean a balance between the pro- and de-pharmaceuticalization impacts of these two groups, and a balanced consideration of both potential harms and benefits. In this case study we explore the possibility of creating a different kind of patient group which might open up new arenas of public discourse relevant to pharmaceuticalization. We focus on the issue of drug licensing, as a context in which the potential benefits and harms of new drugs are formally evaluated; licensing decisions are directly relevant to pharmaceuticalization, as they may increase the repertoire of available drugs. The specific questions we wished to address were how this group of patients evaluated existing mechanisms for licensing drugs; how they balanced scientific and

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