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Growth hormone, enhancement and the pharmaceuticalisation of short stature

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ABSTRACT

This paper takes the biological drug human Growth Hormone (hGH) as a case study to investigate processes of pharmaceuticalisation and medicalisation in configuring childhood short stature as a site for pharmaceutical intervention. Human growth hormone is considered to have legitimate applications in treating childhood growth hormone deficiency and short stature associated with other recognised conditions. It is also regarded by bioethicists and others as a form of human biomedical enhancement when applied to children with idiopathic or 'normal' short stature. The purpose of this study is not to evaluate whether treatment of idiopathic short stature is enhancement or not, but to evaluate how some applications of hGH in treating short stature have come to be accepted and stabilised as legitimate 'therapies' while others remain contested as 'enhancements'. A comparative, historical approach is employed, drawing on approaches from medical sociology and Science and Technology Studies (STS) to set out a socio-technical history of hGH in the US and UK. Through this history the relative influence and interplay of drivers of pharmaceuticalisation, including industry marketing and networks of drug distribution, and processes of medicalisation will be employed to address this question and simultaneously query the value of enhancement as a sociological concept.

1. Pharmaceuticalisation, medicalisation and enhancement

Pharmaceuticalisation describes a process whereby 'human conditions, capabilities and capacities' are (re)configured as sites for intervention with pharmaceutical drugs (Williams et al., 2011, p711). Sociological interest in pharmaceutical use has been increasing in recent years, at least partly in response to significant increases in sales and application of pharmaceuticals since the 1980s (Busfield, 2003; Williams et al., 2008). This interest has manifested through transformations in well-established sociological concepts such as medicalisation (Conrad, 2005) and also in the rise of work on pharmaceuticalisation. Pharmaceuticalisation theorists have argued that a separate theory, linked to but discrete from medicalisation, is required to adequately theorise increasing pharmaceutical use. One argument is that pharmaceuticalisation can occur without accompanying medicalisation – for example when non-pharmaceutical treatments for existing medical conditions are replaced by pharmaceutical interventions (Abraham, 2010). It is also argued that aspects of pharmaceuticalisation occur outside the boundaries of medicine and medical authority. For Abraham (2010, p606) this involves making a distinction between 'biomedicalist' arguments that growth in drug treatment is driven by scientific progress in identifying new pharmaceutical treatments for disease, and alternative non-medical explanations for the expansion in drug use such as 'commercial priorities, government agendas, and false expectations of doctors and patients'. While Williams et al. (2011, p711) present a more constructionist, STS-influenced version of pharmaceuticalisation to Abrahams' realist model, they articulate a similar sentiment, arguing that the processes of pharmaceuticalisation 'extend far beyond the realms of the strictly medical or the medicalised to […] non-medical uses for lifestyle, augmentation or enhancement purposes'. It is this contention that there is a realm, however defined, outside medicine where medical drugs are bring employed for 'non-medical' uses that makes pharmaceuticalisation a relevant analytic tool for examining the phenomenon of human enhancement.

Human biomedical enhancement involves the use of 'drugs, surgery and other medical interventions aimed at improving mind, body or performance' (Conrad and Potter, 2004, p185). Enhancement, by definition, involves an expansion of medical technologies, including pharmaceuticals, beyond the traditional medical role of therapeutic or palliative intervention (Juengst, 1998; Daniels,

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2000). As such, it has been analysed by social theorists through the lenses of medicalisation (Conrad and Potter, 2004; Conrad, 2005) and pharmaceuticalisation (Coveney et al., 2011; Williams et al., 2011; see also Bell and Figert, 2012). The relationship between pharmaceuticalisation and medicalisation theories is not an 'either/or' dichotomy. Relations between processes of medicalisation and pharmaceuticalisation are complex and contextual, ranging from mutual reinforcement to opposition (Abraham, 2010; Williams et al., 2011). Both processes can also be partial and reversible. Given this, it seems more appropriate to investigate the interactions between processes of medicalisation and pharmaceuticalisation in analysing human enhancement, than to focus on pharmaceuticalisation alone.

Another contemporary update to medicalisation theory is also relevant for theorising biomedical enhancement. The biomedicalisation thesis propounded by Clarke et al. (2003) argues that medicine is becoming ever more technological and orientated around bioscientific understandings of the body and of human conditions. The power of biomedicine renders the body pliable as 'an object which can be manipulated, reconfigured, moulded, sculpted and transformed through technoscience' (Coveney et al., 2011, p380). Where medicalisation, it is argued, deals primarily with issues of medical control and normalisation, biomedicalisation emphasises ideas of transformation, choice and opportunities for customisation and enhancement. Thus studies of human enhancement through medicalisation theory must also engage with the questions of whether particular cases of enhancement are better characterised as 'traditional' medicalisation or biomedicalisation, and whether this distinction is analytically useful to the case.

The aim of this paper is to take an empirical case study of a pharmaceutical described as having enhancement uses as a site to investigate the utility of using pharmaceuticalisation (and medicalisation) to gain analytic purchase on enhancement phenomenon. The selected case study is the use of human Growth Hormone (hGH) as a pharmaceutical intervention to increase the adult height of children with short stature.

1.1. Why human growth hormone?

The naturally occurring human growth hormone protein was first isolated from human pituitary glands by American biochemists in the late 1950s. The newly isolated molecule was almost immediately investigated as an experimental intervention for children with abnormally short stature. The first report of a measurable increase in growth rate and height in a short child produced by administration of hGH was reported in 1958 and stimulated efforts to produce and supply the hormone to US paediatric endocrinologists (Raben, 1958; Tattersall, 1996). Although the initial discovery was made in the US, many other countries soon followed suit and set up their own systems of pituitary collection and hormone extraction. Pituitary-derived hGH was primarily used to treat children classified as having severe growth hormone deficiency (GHD) until 1985, when supplies of pituitary hGH were found to have been to be contaminated with biological material causing neurodegenerative effects, and rapidly withdrawn from use.

A biosynthetic version of hGH, produced through the newly-developed technology of recombinantly-engineered cells incorporating the human genetic sequence for the growth hormone protein was pushed through the final stages of regulatory approval and became available by the end of 1985 (Tattersall, 1996). The recombinant hGH was produced by the US firms Eli Lilly and Genentech and marked a transition of hGH into established networks of commercial pharmaceutical production, sales and marketing. In the years following this transition, the patient population for hGH increased significantly, including through off-label use in a range of short statured conditions. For many commentators this expansion reached its zenith in 2003 when the US Food and Drug Administration (FDA) approved Eli Lilly's *Humatrope* brand growth hormone for the treatment of idiopathic short stature (ISS). Treating children with idiopathic short stature, or short stature with no discernable physiological causation, is regarded by many as human enhancement (Tauer, 1995; Daniels, 1992; Conrad and Potter, 2004).

Growth hormone makes a good case study for investigating enhancement for a number of reasons. It is a regularly cited example of a drug that can be used for both normal therapeutic applications and as a form of human biomedical enhancement, providing an opportunity compare pharmaceuticalisation across a legitimated therapeutic use and a contested enhancement application. The story of hGH begins in the mid-twentieth century, meaning there is a relatively accessible record of academic medical articles and pharmaceutical and regulatory 'grey' literature through which to trace the history of ideas and applications of the drug by those most closely involved with it (Weiner, 1988). Additionally, hGH has only received regulatory approval for treating ISS in the US, offering potential for comparative studies of hGH in other regulatory domains.

Conrad and Potter (2004) have also argued that the value of hGH as a case study lies in its multiple enhancement uses, as hGH is also used as an illegal performance enhancer by athletes and bodybuilders and is prescribed off-label as an anti-ageing drug in some private clinics. Although there is merit to this appraisal, this article will focus exclusively on the use of hGH in short stature in order to give this example the in-depth consideration that it warrants and that has, arguably, been lacking in previous social science accounts.

2. Methods

Drawing on the recommendations of Coveney et al. (2011), this study combines perspectives from medical sociology and Science and Technology Studies (STS) to investigate pharmaceuticalisation in the case of hGH. Following an STS perspective, technologies, including hGH, do not appear fully-formed to present ethical dilemmas about their use, but are shaped over the history of their creation, regulation and deployment. Accordingly, this investigation takes the form of a socio-technical history of hGH, tracing its early development, initial application and subsequent expansion including its contested application in ISS children (c.f. Oudshoorn, 1994; Goodman and Walsh, 2001). This history can be traced using the academic medical and 'grey' literature from the appropriate time period. Such an approach avoids taking a teleological 'biomedicalist' perspective on drug development and instead looks at the changing networks, conceptual frameworks and social relations through which hGH became available as a pharmaceutical. In theorising these networks it is also helpful to adopt the concept of a 'pharmaceutical regime' – a particular, more-or-less stable set of networks, ideas and relations through which particular types of pharmaceutical, such as hormone drugs, are produced and supplied (Goodman and Walsh, 1993 cited in Williams et al., 2011).

This particular socio-technical history focuses on the comparative development of hGH in the US and the UK. Against the charge of an excessive focus on 'Western' issues at the expense of the rest of the world (Bell and Figert, 2012), I argue that human enhancement, much more so than the pharmaceutical industry, is at present primarily a Western phenomenon. The concept of biomedical enhancement and many of the technological applications described as 'enhancing' originate in the US, making it an obvious component for investigating pharmaceuticalisation and enhancement, while the UK presents a useful and accessible counter-example, which

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