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Abstract

This paper discusses three concepts from medical sociology – pharmaceuticalisation, corporate bias and the permissive principle – showing how these conceptual tools can be used to analyse bioeconomic fairness and efficiency in relation to the development, regulation and consumption of pharmaceuticals. The three concepts reveal the problematic impacts of the influence and interests of the pharmaceutical industry at various levels of the development, regulation and subsequent use of pharmaceuticals – and, as such, various possible examples of bioeconomic inefficiency and unfairness. First, the paper discusses the concept of pharmaceuticalisation which enables analysis of the social forces that can shape the new or widening usages of pharmaceuticals. It suggests that if social forces, such as medicalisation, consumerism or deregulatory ideology are driving widening or new use of pharmaceuticals then pharmaceuticals in specific contexts might be said to be inefficient solutions. Next, the paper shows how the concept of corporate bias enables analysts to engage with the question of the interests served in pharmaceutical development and regulation. The paper highlights how, due to corporate bias, regulation can work unfairly in the interests primarily of the pharmaceutical industry and to the detriment of patient and public health. Finally, the paper discusses the permissive principle, where benefits are assumed to outweigh risks in pharmaceutical regulation. The presence of permissiveness means that pharmaceutical products that lack benefit or are unsafe may nevertheless achieve regulatory approval – potentially meaning inefficient spending or use of healthcare resources, as well as unfairly serving commercial interests over patient and public health interests.

1. Introduction

The pharmaceutical industry is a central actor in the current organisation of the bioeconomy and pharmaceutical products are one of the key products emerging from biotechnology and bioscience. In the UK, in 2020, the value of the pharmaceutical industry was £40bn – the sector with the largest turnover in the UK life sciences sector (Office for Life Sciences, 2020). The dominant narrative, certainly in neoliberal capitalist societies, is that drug development is the process of developing and marketing pharmaceuticals for objectively identified health problems (Abraham, 2008a). Relatedly, large drug company profits are seen as the by-product of a job well done and are justifiable rewards reflecting risky financial investment in research and development. However, contrary to this narrative, a body of evidence (see Rodwin, 2013a) points to the potentially damaging influence and excessive reliance on the pharmaceutical industry across all dimensions of the development, regulation and consumption of pharmaceuticals (Rodwin, 2013b). Indeed, the pharmaceutical industry is central to the testing and production of medical knowledge about pharmaceuticals (Light et al., 2013), and they have developed intimate connections with ostensibly independent regulators and guideline developers who shape the prescription of pharmaceuticals by medical professionals (Cosgrove and Wheeler, 2013; Sismondo, 2013). In this regard, evidence suggests that vast financial

incentives and the associated commercial interests of the pharmaceutical industry can negatively impact processes designed to ensure that pharmaceuticals that reach the market are safe, effective, beneficial and necessary with an associated fair and efficient use of resources.

This paper discusses three important concepts developed by and deployed in the scholarship of Abraham (1995, 2002, 2008a, 2009; 2010) that enable social analysis of the biomedical narrative that pharmaceuticals are *always* necessary, beneficial solutions to objectively defined medical problems – particularly within psychosocial and lifestyle areas of medicine. As Abraham notes (see 2007: 41-42) pharmaceuticals may be lifesaving products but they can also cause serious adverse reactions in patients – and some drugs have minimal benefit particularly in relation to existing alternatives (both pharmaceutical and non-pharmaceutical). Abraham's work encourages analysis of how social forces, relating particularly to the commercial influence and interests of the pharmaceutical industry may exaggerate, or even distort, the necessity and perceived utility of pharmaceutical products and result in the inefficient use of healthcare funding/resources when compared variously to other existing pharmaceutical products, non-pharmaceutical treatments or no intervention at all.

Considering the theme of this special issue, this paper argues that the concepts of pharmaceuticalisation, corporate bias and the notion of the permissive principle[1] emerging from decades of Abraham's scholarly output encourage and enable crucial social analysis of the fairness and efficiency of the pharmaceutical sector as a significant branch of the bioeconomy nationally and comparatively[2]. Abraham's (1995; 2002; 2008a; 2010) work suggests that pharmaceuticals should be developed and regulated in a manner that provides people with products that they need without undue constraint whilst also ensuring that drugs are effective, safe, necessary and beneficial interventions. To do this pharmaceutical regulation should ensure that the use of state funding and resources in healthcare provision is not wasted on ineffective or dangerous products. In this regard, a healthy bioeconomy should work fairly in the interests of patient and public health and not solely or primarily for commercial gain. The three concepts, in their own specific way, enable analysis of whether bioeconomies are operating in this manner.

Abraham's body of work within the sociology of pharmaceuticals research area dates back three decades and is comprised of many journal papers and a range of books where he has analysed evidence of the problematic influence of the pharmaceutical industry on the growing consumption of pharmaceuticals – with his work attracting thousands of citations. Abraham's impact also stretches beyond academia. For example, he provided expert advice to the House of Commons Health Select Committee (2005) who published a report detailing the findings of a landmark investigation into the influence of the pharmaceutical industry on the growing use of pharmaceuticals and the associated disadvantages (including excessive medicalisation and seemingly growing rates of adverse events). In this regard, Abraham is a highly influential scholar analysing how the influences and interests of the pharmaceutical industry shape the nature and functioning of modern biomedicine whilst contributing to the associated attempts by the British government to understand the issue and ostensibly develop an effective policy response.

The primary contribution made in this paper is to act as an introduction to the work of Abraham's influential and vast body of scholarship. The three concepts explored in this paper are central to understanding Abraham's arguments – however, they emerge in different outputs and at different stages of Abraham's career. This paper aims to provide a streamlined

[1] The three concepts overlap and interlink in Abraham's work – but this paper discusses them separately for the sake of clarity with the aim of delineating clearly how the concepts can be analytically deployed.

[2] The bulk of Abraham's work has focused on the US, EU and UK contexts but the concepts can be used to analyse other neoliberal contexts.

introduction to and review of the most important dimensions of Abraham's scholarship, whilst asserting the utility of three of Abraham's conceptual tools in the analysis of the more general state of bioeconomic fairness and efficiency – and, in turn, encourage further empirical research drawing on his work. This paper now turns to explore in turn the analytic value that the concepts of pharmaceuticalisation, corporate bias and the permissive principle possess.

2. Pharmaceuticalisation

The first concept that can enable examination of bioeconomic fairness and efficiency is pharmaceuticalisation which is defined 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: 604). It is important to note that pharmaceuticalisation has a couple of different articulations by separate authors and to some degree is entangled or competes with the broader concepts of medicalisation and biomedicalisation which focus on more general issues beyond pharmaceuticals including the expansion of the (bio)medical realm. Some work suggests that there is no need for the newer concepts of biomedicalisation or pharmaceuticalisation to be used alongside or instead of the older concept of medicalisation, rather that medicalisation can be updated to analyse new drivers of a widening medical realm, notably the pharmaceutical industry (Conrad, 2005). However, the specificity of pharmaceuticalisation arguably increases its analytic utility when examining the expanding usage of pharmaceuticals (which can occur without any new medicalisation) (see Douglass and Calnan, 2022a for a broader discussion). Abraham's conceptualisation of pharmaceuticalisation is centrally concerned with assessing the impacts and outcomes of pharmaceutical development, regulation and provision.). He argues, in other words, that creating opportunities for new or widening uses of drugs can and should be assessed against whether (or not) it meets real, objective medical need. In this regard, his approach is valuable for assessments of bioeconomic fairness and efficiency as it enables analysts to examine whether new pharmaceuticals or new uses of existing drugs are an objectively necessary use of funding/resources and relatedly beneficial for patient and public health.

Abraham argues that to assess whether new pharmaceutical products or new applications of drugs are being fairly and efficiently developed, regulated and consumed they must be analysed against competing explanations. He argues that increasing use of pharmaceuticals may be less well explained by the dominant biomedical narrative of meeting objective need than by the social forces of medicalisation and industry promotion, consumerism, and deregulatory policies which may serve to create 'need'. In this regard, Abraham establishes the potential importance of sociological components fostering, particularly in some examples of psychosocial and lifestyle areas of medicine, "false claims and expectations about the capacity of pharmaceuticals to meet [health] needs" (2010: 617).

First, Abraham argues that medicalisation, which is the process of applying medical labels to social problems, may also be a better explanation than the dominant biomedical narrative for the widening availability and use of pharmaceuticals. For example, in the case of attention deficit hyperactivity disorder (ADHD) thresholds of what is considered 'normal' behaviour have been lowered so much that some studies suggested that 50% of all children could meet symptom criteria despite studies designed to identify the biochemical bases for ADHD suffering from problems of rigour and replicability, whilst the deviation of people diagnosed with ADHD from 'normal' levels of dopamine is contentious. Importantly, Abraham argues that the medical elites involved in defining or widening diagnostic categories are often associated with or funded by the pharmaceutical industry. In this regard, rather than pharmaceuticalisation reflecting the diagnosis of objective medical need, research and disease-awareness campaigns funded by industry may "have exaggerated the benefits of drugs, such as SSRIs, tranquillizers and Viagra, resulting in them being prescribed in ways that have no

techno-scientific basis" (Abraham, 2010: 609). Furthermore, Abraham shows that the pharmaceutical industry has also engaged in practices, such as ghost writing or editing scientific manuscripts to give the appearance of greater medical benefit, withholding negative data whilst also undermining critics and removing funding from institutions employing critical scholars. All of this is designed to uncritically result in the reframing of problems as requiring pharmaceutical treatment. This argument suggests that some new and widening diagnostic categories and the associated prescription of pharmaceuticals are not necessarily about the efficient meeting of objective health need and instead reflective of the pharmaceutical industry's influences on the evidence base – with the industry motivated by vast potential profits – as well as relationships with medical elites and professionals who interpret the evidence and prescribe drug treatments.

Next, Abraham shows how consumerism can be a driving force behind pharmaceuticalisation rather than the objective, efficient and fair meeting of need suggested by the dominant biomedical narrative. He identifies two types of consumerism. In simple terms, access-oriented consumerism (such as campaigning for access to new drugs) can drive pharmaceuticalisation, whilst injury-oriented consumerism (e.g. legal action taken due to harm caused by drugs) can limit or prevent pharmaceuticalisation. Though acknowledging the rise of the patient-consumer and consumerist principles within healthcare more generally, Abraham argues that access-oriented consumerism, where the interests of consumers align with the interests of the pharmaceutical industry, is likely to be much more successful than injury-oriented consumerism. In this regard, consumerism, though sometimes leading to de-pharmaceuticalisation, is more likely to support or drive pharmaceuticalisation. Indeed, Abraham discusses how consumer groups working in allegiance with or funded by the pharmaceutical industry to access pharmaceuticals with disputed evidence bases have often successfully pressed for access to expensive drugs funded through the NHS (see Abraham, 2009). This argument suggests that the influences and relationships of the pharmaceutical industry may result in a build-up of pressure that results in the possibly inefficient use of resources.

Abraham, finally, discusses the centrality of deregulatory ideology in driving pharmaceuticalisation. He notes that pharmaceutical product innovation has declined in the years that lifestyle and psychosocial areas have seen increasing pharmaceuticalisation. As such, growing use of pharmaceuticals cannot necessarily be explained by growth in techno-scientific discovery/advance, or, as such, the dominant biomedical narrative. This decline in innovation is likely to be associated with de-regulatory tendencies within regulatory organisations from the 1980s onwards that have lessened the burden on the industry to be innovative, particularly because new drugs do not have to show therapeutic advance over existing drugs. This is interesting because arguments by industry and those in government for lessening the regulatory standards have been rooted in claims that overwhelming regulatory burdens have restricted innovation. This argument suggests that deregulatory ideology is driving the development and use of some types of pharmaceuticals rather than the alternate thesis that objective need always leads to the new, efficient and fair utilisation of pharmaceutical products based on objective need.

3. Corporate bias

The second concept that this paper argues can facilitate examination of bioeconomic fairness and efficiency is corporate bias. Abraham (2008a) argues that at a

"particular time in pharmaceutical development and regulation there are techno-scientific regulatory standards, whose publicly declared purpose is to protect and promote public health by ensuring that drug products are adequately safe and efficacious. Methodologically, those standards can be deployed by sociologists to investigate

how well, in practice, pharmaceutical testing and regulation act in the interests of public health, and how far they are influenced by commercial or other interests"

In this regard, he argues that there is evidence that patient and public health have real interests in medicines having an optimal benefit-risk ratio, whilst the pharmaceutical industry has an objective interest in the maximisation of their profits. Abraham argues, however, that pharmaceutical development and the regulation of pharmaceuticals, which ostensibly exists to protect public health, has sometimes failed to maximise the interests of patient and public as a result of what he calls corporate bias. In this regard, this concept encourages analysis of the interests that are dominant in pharmaceutical development and regulation, and in this sense, how fair the process is for all interested parties.

The concept of corporate bias, which is based in an objective interest-driven framework against which action and behaviour can be analysed, suggests that

the pharmaceutical industry was, and is, permitted to have privileged strategic access to, and involvement with, government regulatory policy over and above any other interest group; and more often than other factors, the industry was, and is, decisive in determining regulatory policy outcomes (or lack thereof). The regulatory state and the pharmaceutical industry work largely in partnership and behind a cloak of secrecy.

Bias, in this context, "is defined as a consistent trend or pattern of technical inconsistencies or contradictions mapped on to a set of social interests". These technical inconsistencies or contradictions can mean that the techno-scientific standards of pharmaceutical development and regulation are biased by commercial interests away from the stated purpose of these standards which is to ensure drugs are safe and hold efficacy, and in the process, protect public health. This reflects, for example, the fact that drug regulators (such as the Medicines and Healthcare Products Regulatory Agency, the MHRA, in the UK, the European Medicines Agency, the EMA or the Food and Drug Administration, the FDA, in the US) are either largely or solely funded by fees they receive from pharmaceutical companies. To be clear, this means that pharmaceutical companies pay regulators to assess the efficacy, safety and quality of their products before marketing meaning in essence that pharmaceutical companies are customers of the regulators (see Calnan and Douglass, 2017 for a more detailed discussion of the processes of drug trialling and regulation; see also Calnan and Douglass, 2020; Douglass and Calnan, 2022b).

A programme of research by Abraham and colleagues has demonstrated the extent of corporate bias present in pharmaceutical regulation using historical and international comparative analyses. Indeed, bringing a new drug to the market is a costly exercise and the pharmaceutical industry has sought ways of decreasing costs and duration of development. In this regard, the industry has attempted to harmonise regulatory standards (which, to remind the reader, ensure that drugs are safe, of sufficient quality and hold efficacy) to access markets simultaneously and reduce the overall regulatory burden (Abraham, 2008a). Research has shown that the subsequent harmonisation that has occurred has ultimately led to decreased regulatory standards with fewer safety checks on new drugs resulting in quicker and less robust processes for bringing drugs to the market (Abraham and Reed, 2002; 2003). This is clearly to the benefit of the pharmaceutical industry but not necessarily patient and public health. This demonstrates how the pharmaceutical industry under the guise of greater efficiency has sought to make the development and regulation of pharmaceuticals less fair, rigorous and protective of patient and public health and to greater commercial benefit. It is here that value of the concept of corporate bias when analysing matters of the bioeconomy is clear as it reveals the corporate interests served by claims to regulatory 'efficiency' or regulatory developments/reforms claiming to increase 'efficiency'.

Abraham (2009) additionally explores how corporate bias has shaped the 'fourth hurdle' of pharmaceutical regulation concerned with cost-effectiveness (Timmins et al., 2016). In the UK, cost effectiveness evaluation of medical technologies including pharmaceuticals is conducted by the National Institute for Health and Care Excellence (NICE) rather than the MHRA (who, as noted, focus on the initial three regulatory 'hurdles' assessing the efficiency, safety and quality of pharmaceuticals). NICE conduct clinical and economic evaluations of whether pharmaceutical interventions can be justified based on expected costs over another intervention or decision to do nothing in terms of health impacts. In simple terms, they ask how well treatment works in relation to how much it costs the NHS. Consistent with the problem of corporate bias, Abraham (2009) shows that in most cases NICE only have access to published data (which, due to various industry practices, may has not always given the full picture). This has meant, for example, that SSRI antidepressants were initially considered appropriate for use in children based on the published evidence and thus accessible through the NHS. However, this was reversed when NICE gained access, in an uncommon occurrence, to the unpublished data. Abraham's (2009) work here suggests that cost effectiveness regulation may not, as such, always lead to the efficient use of healthcare funding/resources under typical circumstances and may be biased away from working fairly in the interests of public health.

4. The permissive principle

Another important contribution in the work of Abraham and colleagues relevant to understanding bioeconomic fairness and efficiency is that of the use of the 'permissive principle' in the analysis of pharmaceutical development and regulation (Abraham, 2002; Abraham and Davis, 2009). The permissive principle is defined by the assumption that the benefits are said to outweigh risks of a pharmaceutical product unless substantial evidence of harm exists (Abraham, 2002: 20) and the "tendency to allow a drug on the market despite it not meeting established standards of efficacy or safety" (Abraham and Davis, 2009: 570). The opposite and more traditional understanding of clinical trials and regulation, the precautionary principle, begins instead from the assumption that the regulatory standards are established because they are most able to assess harm. In this regard, in applying critiques of permissiveness the burden of proof falls on those of who argue new pharmaceutical products to be unsafe (Abraham, 2002). A precautionary approach is likely to require more considerable evidence of safety and benefit, particularly where alternate treatments might be available (Abraham, 2002).

Regulatory trust is an important component underpinning permissiveness. Abraham (2008b) outlines two forms or norms of regulatory trust known as investigative and acquiescent trust. The former is suggestive of trust relationships that result in a thorough assessment of company data (and the anticipation of this by industry), with the latter suggestive of trust relations that mean pharmaceutical industry data will be accepted relatively uncritically. Abraham suggests that in countries such as the UK and US the underpinning norms of regulatory trust have shifted away from investigative towards acquiescent. This, Abraham suggests, reduces the incentives for the pharmaceutical industry to conduct adequate trials. Shifts in norms of regulatory trust are visible clearly in trends towards accelerated drug approvals as has been the case for cancer drugs in certain contexts (Davis and Abraham, 2011).

Evidence suggests that the permissive principle has featured in the regulation of pharmaceuticals over time (Abraham, 1995; Abraham and Sheppard, 1999) and often involves regulators violating their own established technical standards (Abraham and Davis, 2009). For example, in the case of triazolam (Halcion) a controversial hypnotic, in the US context in the 1990s, Abraham (2002) shows how the permissive principle functions. Anecdotal evidence (despite lack of compelling RCT data) was utilised to confirm efficacy by expert committees in the USA at the Food and Drug Administration (FDA) and the Institute of Medicine, whilst

simultaneously RCT evidence was required to confirm a lack of safety. Selectiveness in the use and type of evidence here, to the overall approval benefit of the drug and pharmaceutical industry, is suggestive of permissiveness. Overall, if benefit is assumed to outweigh risk, with a heightened burden on attempting to disprove benefit over risk, and/or some undermining of a body's own technical standards, the permissive principle, as discussed by Abraham (2002) and Abraham and Davis (2009), can be said to have explanatory power. In this regard, if the permissive principle is shown to be present in regulatory activity, there will also be possibly inefficient uses of healthcare funding and resources occurring. Abraham's use of the permissive principle also suggests that regulation may not be working in the interests of patient and public health, for example, due to the violation of their own technical standards – and thus is operating unfairly.

5. Conclusion

This paper has outlined three important concepts – pharmaceuticalisation, corporate bias and the permissive principle – developed and utilised in the work of Abraham (1995, 2002; 2008a; 2010) that can be deployed to analyse the state of bioeconomic fairness and efficiency (both historically and in the present) as relates to the products developed and regulated in the pharmaceutical sector. It has been the purpose of this paper to assert the considerable value of Abraham's scholarship, examine and explain the utility of his conceptual apparatus and thus to encourage and enable further empirical analysis of bioeconomic fairness and efficiency. Though the focus has primarily been conceptual, this paper has provided a range of examples of the ways in which western, neoliberal bioeconomies have operated in an unfair and inefficient manner.

First, this paper has discussed the concept of pharmaceuticalisation which encourages analysis of the social forces that can explain the new or widening usages of pharmaceuticals rather than objective need and benefit for patients. If social forces, such as medicalisation, consumerism or deregulatory ideology are driving the widening or new use of pharmaceuticals then specific pharmaceutical products might be said to be inefficient solutions. Next, the concept of corporate bias enables analysts to engage with the question of the interests served by pharmaceutical development and regulation – with Abraham suggesting that, due to corporate bias, it often works unfairly in the interests primarily of the pharmaceutical industry and to the detriment of patient and public health. Finally, the permissive principle, where a narrative is adopted in regulation of benefits being assumed to outweigh risks, similarly enables analysis of the fairness and efficiency of regulation and thus the functioning of the bioeconomy. Rooted in acquiescent trust relationships between industry and regulators, the presence of permissiveness means that pharmaceutical products that lack benefit or are unsafe may nevertheless achieve regulatory approval – potentially meaning inefficient spending or use of healthcare resources, as well as unfairly benefiting commercial interests over patient and public health interests.

Other scholars working within the sociology of pharmaceuticals (see Douglass and Calnan, 2022 for an overview of this literature) have suggested that Abraham's realist approach – which centres analysis of necessity and interests – can lead to analysis that neglects the different values and patient choices associated with pharmaceutical consumption, whilst also suggesting that the importance of the roles played by patients and patient groups in pharmaceutical innovation and desire for new drugs may have been underappreciated in Abraham's work. This body of work additionally suggests that Abraham's approach to the analysis of pharmaceuticalisation may lead to an analytical neglect of the benefits and positives for patients and the bioeconomy (with similar criticisms made of older scholarship concerned with medicalisation – see Williams and Calnan, 1996). However, as this paper has demonstrated, analysis drawing on Abraham's three concepts points to the problematic impacts

of the influence and interests of the pharmaceutical industry at various levels of the development, regulation and subsequent use of pharmaceuticals – and, as such, various possible examples of bioeconomic inefficiency and unfairness in neoliberal societies. In this sense, there is clear value in the focus of and approach taken in Abraham's work.

In the years since the three concepts discussed in this paper emerged, there have been attempts to prevent or limit the extent to which the interests of the pharmaceutical industry can influence the development, regulation and medical use of pharmaceuticals. This has occurred in relation to the implementation of more stringent ethical and regulatory requirements, including the need to register clinical trials and a growing emphasis on the importance of the disclosure of conflicts of interest by regulators, guideline developers and doctors (see Cosgrove and Wheeler, 2013 and Sismondo, 2013 for further discussion). Despite these positive steps, due to the control of and dependency on the pharmaceutical industry throughout the phases of drug development and regulation it has proven difficult to radically reform the sector. It is also important to note that pharmaceuticalisation (particularly of psychosocial and lifestyle phenomena) continues to increase/widen. For example, in the UK in recent years already widely prescribed medicines taken by millions, such as statins (drugs used to lower cholesterol and reduce the risk of cardiovascular disease) have been offered to millions more people as a result of reanalysis of what is considered sufficient risk of developing cardiovascular disease (see Wise, 2014). It is true that in psychiatry, there is a growing critique of biomedical understandings of mental illness – such as a recent analysis that challenges the narrative of depression as caused by a 'chemical imbalance' (Moncrieff et al., 2022; see also Davies, 2021: 37-74). As this debate continues, social scientists could use Abraham's concepts to usefully engage with, for example, the social driving forces of pharmaceuticalisation in psychiatry in the apparent absence of a biomedical abnormality that drugs like antidepressants can address.

Overall, the three concepts discussed in this paper are highly useful tools for social scientists to unpick how the industry's influence, relationships and interests might harm bioeconomic efficiency and fairness in specific cases, in a range of regulatory contexts internationally, and comparatively. In this regard, social scientists drawing on Abraham's scholarship can make a salient contribution to continued reform efforts and increased efficiency and fairness in the pharmaceutical sector.

Acknowledgements

Thank you to guest editor Joy Zhang for inviting me to write this paper and to two anonymous reviewers for their constructive suggestions.

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