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Article:

Chico, V., Hervey, T. orcid.org/0000-0002-8310-9022, Stirton, R. et al. (1 more author) (2014) *Markets and Vulnerable Patients: Health Law After the 2012 Act*. *Medical Law Review*, 22 (2). pp. 157-161. ISSN 0967-0742

<https://doi.org/10.1093/medlaw/fwu013>

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MARKETS AND VULNERABLE PATIENTS: HEALTH LAW AFTER THE 2012 ACT

Editorial

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MARKETS AND VULNERABLE PATIENTS: HEALTH LAW AFTER THE 2012 ACT

In the popular imagination, the Health and Social Care Act 2012 is associated with a final ‘dismantling of the NHS as we know it’, by bringing competition, markets, contracts, and private interests in to the NHS.¹ The Bill’s turbulent journey through the Parliamentary process (more than 1000 amendments; over a year in debate; multiple attempts to block, stall or delay the Bill, up to the last minute) shows how controversial such a move was understood to be. This process also took place at a time when, in view of numerous inquiries, public trust in the ability of English healthcare institutions (in particular hospitals, but also nursing homes) to protect vulnerable patients against fundamental failures to provide compassionate care and treatment had been seriously undermined.

The Act came into force on 1 April 2013. While doing so is reminiscent of Monty Python’s Summarise Proust Competition², the key provisions can be summarised as follows. The Secretary of State for Health remains accountable to Parliament for health service provision,³ while many responsibilities historically located in the Department of Health are now placed on other bodies, such as Monitor, the NHS Commissioning Board (‘NHS England’), and around 200 ‘clinical commissioning groups’, integrating innovation through 15 new Academic Health Science Networks. Monitor is the new health-specific economic regulator, and is responsible alongside the Office of Fair Trading, for ensuring that ‘qualified providers’⁴ of health services comply with competition law.⁵ Monitor will also regulate prices⁶ and has a duty to work with commissioners to ensure continuity of care in the event that a

¹ See, for instance, Youssef El-Gingihy, ‘Health Act means the death of the NHS as we know it’ *The Observer* (London, 30 March 2013) <<http://www.theguardian.com/commentisfree/2013/mar/30/health-act-means-death-of-nhs>> accessed 13 March 2014

² Monty Python Summarize Proust Competition (Youtube) <<http://www.youtube.com/watch?v=uwAOc4g3K-g>> accessed 13 March 2014

³ Health and Social Care Act 2012, s 1(3)

⁴ Licensed under Health and Social Care Act 2012, ss 81-114

⁵ Health and Social Care Act, ss 61-80

⁶ *ibid*, ss 115-127

provider exits the market.⁷ NHS England takes over from strategic health authorities and primary care trusts, both of which are abolished.⁸ Clinical commissioning groups,⁹ which are consortiums of GPs, and local authorities, will commission integrated health and social care services, through 'Health and Wellbeing Boards'.¹⁰ These new bodies will control nearly 70% of the NHS budget for health services.¹¹ Providers of health services must be licensed, but the policy of 'any qualified provider'¹² seeks to make it easier for third sector and private organisations to enter a market for NHS service provision.

This special issue brings medical lawyers together with those with an interest in health as a case study, but who self-define as competition lawyers, EU lawyers, pharmaceutical and patent lawyers, comparative lawyers, bioethicists, empirical socio-legal scholars, or regulation specialists. We hope to make four, interconnected, contributions to health law scholarship, while also exploring how the post-2012 Act position affects or might affect vulnerable patients.

First, using the 2012 Act as a springboard, we explore some of the dynamics between health understood as a social public good and health understood as a marketable commodity, and the implications of those meanings for vulnerable patients and health law scholarship. The view of health as a social public good is inherent in the classical approach of medical lawyers to questions of how the law can facilitate choices that might achieve high quality, patient-focused healthcare. For example, Christopher Newdick's article argues that patients – particularly vulnerable patients – are ill-served by governance models based on choice and competition. The 2012 Act questions the assumption that competition, markets, contracts

⁷ *ibid*, ss 98-99

⁸ *ibid*, s 9, sch 4.

⁹ *ibid*, ss 10, 13-14, 20, 24-28, 46, 75, sch 2

¹⁰ *ibid*, ss 193-199

¹¹ ___, 'NHS Allocations for 2013/14' (NHS England) <<http://www.england.nhs.uk/allocations-2013-14/>> accessed 13 March 2014

¹² ___, 'Any Qualified Provider' (NHS Choices) <<http://www.nhs.uk/choiceintheNHS/Yourchoices/any-qualified-provider/Pages/aqp.aspx>> accessed 13 March 2014

and private interests are detrimental to health law. Taken cumulatively, several articles in this issue challenge this classical approach to medical law. For example, Lindsay Stirton's 'long view' article calls into question any 'easy solutions' – such as those embodied by a notion of the 'golden days' of a pre-1990s NHS, governed through hierarchy – as being inherently preferable to markets.

The 2012 Act is pushing the limits of acceptability in conceiving of NHS health services as a market, but commerciality and innovation are not necessarily a panacea for success. Shannon Gibson and Trudo Lemmens' article highlights the critical importance of using the right regulatory tools at the right juncture if healthcare services are to meet increasing public demands for timely access to innovative drugs. In the face of an increasingly fragmented pharmaceutical industry – which is not alone in providing direct-to-consumer healthcare information, products and services – we must question our perceptions of healthcare providers. Sigrid Sterckx and Julian Cockbane's article prompts consideration of whether the 2012 Act presumes an archaic understanding of healthcare providers as both institution-centred and nationally limited.

Secondly, we seek to enhance a dialogue through which the 'classical' methodologies of medical law might be supplemented, or challenged, by the research questions and methodologies of those with another disciplinary focus. By including articles adopting methodologies inspired by comparative and EU law, we explore the lessons that England can learn from jurisdictions that have adopted similar reforms. We also use the 2012 Act to consider how the over-arching framework of European Union law interacts with national health law. Johan van de Gronden and Erika Szyszczak's article shows how key concepts in competition law, such as the notion of an 'undertaking', 'geographic market', or 'market failure', are translated into the context of health law by national authorities. Far from EU competition law being a totalising force, driving European healthcare systems away from a patient-care focus, in some contexts legal categories can be – and have been – used to shield health providers from EU competition law, or to articulate arguments that resonate

with values expressed as promoting high quality, patient-focused healthcare. Written by a 'health lawyer who focuses on the right to health care' and a 'competition lawyer concentrating on health care', André den Exter and Mary Guy's article on the Netherlands exemplifies the benefits of such collaborative scholarship. Their conclusion is that blanket pronouncements about whether markets are 'good' for vulnerable patients are suspect: the context is what matters. However, they agree that marketised healthcare systems are unlikely to address health inequalities.

Thirdly, the ethics-driven focus of medical law, and the perspective of those who seek to introduce greater competition into the NHS, must accommodate the interests of vulnerable patients. Everyone is vulnerable when relying on others for medical, health or social needs, but some groups are particularly vulnerable within this context. For instance, most of the excess deaths in the 14 hospitals in the Keogh review¹³ because of their outlying mortality statistics were older people who may have had complex conditions. The articles brought together here offer an opportunity to think about how the post-2012 Act environment might address failures of health services to provide the ideal of high quality, cost-effective care, centred on the vulnerable user. The articles by Newdick, Stirton, van de Gronden and Szyszczak, and den Exter and Guy all contribute to that debate.

The ethical analysis is more directly exemplified within Gibson and Lemmens' article, prompting consideration of the balance between the needs of individual healthcare improvements and the systemic cost-effectiveness of current regulatory structures. This is exacerbated in the UK by the need to regulate for quality and comparative efficacy. The turn to post-market regulation, and greater transparency, has been hampered, inter alia by legal arguments based on commercial interests being articulated as human rights. For Sterckx and Cockbane, in a healthcare system premised on trust, tensions between the altruism of patients/participants and the potential for commercialisation, the intention to harvest NHS

¹³ Professor Sir Bruce Keogh, 'Review into the Quality of Care and Treatment Provided by 14 Hospital Trusts in England; Overview Report' (NHS England) p. 28 <<http://www.nhs.uk/NHSEngland/bruce-keogh-review/Documents/outcomes/keogh-review-final-report.pdf>> accessed 13 March 2014

patient data, and the questionable practices of some direct-to-consumer genetic testing companies show how we are all vulnerable to abuses.

Finally, we seek to contribute to a debate about how the classical interests of medical law can be re-framed in this post-2012 Act environment. Nothing is more ‘classical’ for a medical lawyer than a clinical negligence claim, and Linda Mulcahy’s article discusses how the nature of clinical negligence has changed since the introduction of the NHS Litigation Authority, and considers how it will develop further in the post-2012 Act regime. Clinical negligence is increasingly seen as, and is performing as, a regulatory safety valve in its own right, especially in the context of information gathering about systemic failures. Mulcahy foresees a valuable role – albeit one controlled by the NHS – for negligence litigation to develop the law in the post-2012 Act regime.

In addition to our four contributions to health law, we illuminate promising future research agendas. They focus around four topics. (a) The optimal blend between regulated markets and individual litigation to protect vulnerable patients. In its choice to introduce a limited opt-out collective actions regime, the government has indicated that collective actions under the competition framework are a viable option for protecting vulnerable patients, especially those affected by competition scandals.¹⁴ It is worth considering whether a well-organised class action in competition will offer better protection than an individual claim in negligence. It will be important to explore the role that negligence actions play in the post-2012 Act regime, since there are clear indications that they are already performing the information gathering functions central to a regulatory regime. (b) The appropriate ways for scholars to analyse systemic failures in the provision of compassionate care. Human rights might be a useful lens for these purposes, since it is far from clear how the Mid-Staffs patient claiming a breach of Article 3 ECHR would fare before the European Court of Human Rights.

¹⁴ See Department for Business Innovation and Skills, *Private Actions in Competition Law: A Consultation for Options on Reform – Government Response* (BIS/13/501, 2013)

Alternatively, the law of negligence may be a more relevant framework, especially in the context of a health law grounded in tort. The main challenge here is articulating the nature of the harm in a way recognised by the law,¹⁵ and in a way such that issues which should be found to be negligent are not dismissed at the causation stage. (c) The appropriate use of confidential patient information, and whether that includes use not directly related to patient care. There is at least the potential for a claim under Article 8 ECHR, which bears exploration. (d) While competition law purports to have general application, it is worth exploring whether incorporating the traditional concerns of medical lawyers – the doctor-patient relationship, patient autonomy, confidentiality, vulnerable patients – can make competition law richer and more coherent in its application in the health context.

Ultimately, this special issue shows that we should reconsider the contrast between the assumption of competition law or market-based regulatory models that the greed and self-serving behaviour of powerful actors has to be guarded against, in order to protect the vulnerable consumer; and the assumption of medical law that it protects the vulnerable through its roots in moral principles, traceable to the Hippocratic Oath and followed through its reformulations in the Declaration of Geneva, and articulated through compassion and trust. The Francis Reports¹⁶ put the assumption that healthcare in the NHS is guided by such compassion and trust on very shaky ground. This alone should be enough to suggest that health law has much to learn from continued collaborations with others.

¹⁵ This may not always be a problem. Some of the patients at Mid-Staffs died as a result of neglect.

¹⁶ The Mid Staffordshire NHS Foundation Trust Public Inquiry, *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (HC 2012-13, 898 I-III)