

# Governing Genomics: New Governance Tools for New Technologies?

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*This note<sup>1</sup> considers some of the “new tools of governance” and how they might apply to the life science industries. Through a study of a number of UK government-industry “task forces” and recent world events in drug regulation it identifies two opposing trends in play and suggests that there are actually limits to the all pervasive notion of governance. Instead, the multi-faceted policy and regulatory situation that applies to the life sciences is leading to the existence of a government-governance continuum where different aspects of genomics and life science technologies sit at different points; contrasting the role of the state in controlling and framing the context for the implementation of innovations in life sciences through the regulatory system with the more participative forms of policy-making that are being fostered both to promote national competitiveness and encourage public acceptance of these new technologies.*

## THE NEW TOOLS OF GOVERNANCE

We begin by considering some of the “new tools of governance”<sup>2</sup> and how they might apply to the life science industries. Based on a study of a number of UK government - industry “task forces” we have examined the extent to which their activities might exemplify this “new mode of governance”. Of paramount interest is the influence of the pharmaceutical industry. When we juxtapose these task forces against examples from other events in the regulation of the life sciences we identify two opposing trends in play.

On the one hand, national and supra-national governments such as the European Union seek to use the life sciences industries as an engine for growth and international competitiveness and recognise the importance of engaging industry stakeholders in the development and implementation of policy in increasingly open forms of governance.

But, on the other hand – running contrary to this – is a concern that the industry has become too influential so we are, at the same time, witnessing counter measures by government to reassert the tools of control via the pharmaceutical regulatory regime.

We conclude that there are actually limits to the all pervasive notion of “governance” and that, instead, the multi-faceted policy and regulatory situation that applies to genomics (and the life sciences more generally) means that we need a mix of policy tools.

Rather than witnessing the total abandonment of a centralised, *governmental* approach in favour of a decentralised *governance* approach what we have is a government-governance continuum where different aspects of genomics policy are located at different points along this spectrum.

It is useful to define a few concepts as the term “governance” can be used to mean many different things at the hands of different authors. But most people would accept that the term “governance” refers essentially to the increased role of non-government actors in policy-making. It is generally regarded as implying an increasingly complex set of state-society relationships where networks, rather than hierarchies, dominate the policy process.

*We are witnessing the emergence of new modes of governance that advocate an increasing role for non-government actors in the policy-making process and the consequent blurring of the boundaries both between and within the public and private sectors*

*The term “governance” is used as shorthand to describe the changing nature and role of the state and the changing boundary between state and civil society*

In this approach, the role of the state changes from being the main provider of policy to one of facilitating interaction among various interests so that government's role is increasingly one of co-ordination and steering multiple actors and institutions to debate, define and achieve policy goals.

From a governance perspective the process of governing is an interactive one because no single actor has the knowledge and resources to tackle problems unilaterally.

That said, many people would argue that the centralised, bureaucratic state still dominates, particularly in sensitive, contentious policy areas like the life sciences. Some challenge the assumption that the growth of networks leads to more democratic government<sup>3</sup> while others<sup>4</sup> suggest that states may have an interest in promoting policy networks, arguing that they “make policy-making predictable and reduce policy conflicts” – a point we shall return to when discussing our study of the taskforces.

Others have pointed out that networks can be closed to outsiders, unrepresentative and can limit participation in the policy process.

So if we accept that the choice of governance tool is essentially still a political decision, how do we ensure an effective mix of policy tools and an appropriate set of governance actors to be involved in that policy network?

## **TASK FORCES – A NEW TOOL OF GOVERNANCE?**

Improving policy design through undertaking stakeholder involvement initiatives has become a key part of UK policy-making. One very visible method of industry involvement in UK policy-making over the last decade or so has been via a number of “taskforces”.

The empirical part of this study examined the operation of three such government-industry groupings relevant to the regulation of the UK life sciences:

- Pharmaceutical Industry Competitiveness Task Force
- Bioscience Innovation and Growth Team
- Healthcare Industries Task Force

The research drew on documentary analysis of their published reports and interviews with some of the taskforce members and other relevant commentators from industry and the policy-making community. The research sought to explore whether these taskforces exemplified “the hollowing out of the state” and might be considered a new tool of governance.

While this industry involvement in government taskforces is clearly regarded as adding gravitas and credibility, some would say that such taskforces are often less about participatory democracy and much more about image management and policy delivery. So can such transitory assemblages of “experts” ever be considered a new tool of governance?

Others would say that rather than devolving power, taskforces reinforce central control, describing taskforces as “the epitome of steering rather than rowing”<sup>5</sup>. Sceptics might extend the boating analogy a bit further and say that they can sometimes seem more like bailing by a government keen to shift some of the responsibility and (dare one say) blame, for certain policy decisions.

So, taskforces certainly underpin the current UK government's approach to governance with its stated focus on policy integration and partnership and we certainly appear to be seeing evidence of greater industry involvement in policy-making. But there are issues about who sets the agenda for these taskforces and also the transitory nature of these groupings which raises the question of whether such taskforces equate entirely with the idea of a new tool of governance.

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*There are clearly tensions in this approach as evidenced by the substantial body of literature on the dangers of regulatory capture by industry*

## THE INFLUENCE OF BIG PHARMA

One could also argue that there has long been a partnership between government and the pharmaceutical industry and that the evidence is simply more visible, rather than that the involvement and interaction are greater.

There are clearly tensions in this approach as evidenced by the substantial body of literature on the dangers of regulatory capture by industry. This is highlighted by, for example, the UK Health Select Committee's inquiry into the influence of the pharmaceutical industry in 2004 and the Vioxx incident in the US concerning post-approval drug safety and the significant impact this had on industry-government relations.

Towards the end of 2004 evidence began to emerge that the anti-inflammatory drug Vioxx was implicated in increased heart risks. There had been safety questions surrounding Vioxx for some time and Merck, the manufacturers, voluntarily withdrew its product and strenuously denied that it had manipulated safety data during the clinical trials phase. Critics said that this was clear evidence that the US drugs regulator was too friendly with industry: what was significant about this case was the impact that it had on the US Food and Drug Administration (FDA).

The Vioxx case raised fundamental questions about drug regulation in the US and the lack of separation between industry and the FDA as a whole. It exposed the US drug regulator to scrutiny by the media and politicians and led to structural reforms within the agency. In particular, it placed the spotlight on the fact that industry controls and finances most of the clinical trials on which FDA decisions are based. This raised questions about independence and regulatory capture: contrary to the generally deregulatory climate, US politicians demanded tighter controls to prevent conflict of interest and ensure greater transparency.

These examples also illustrate how readily mutual government-industry policy co-operations can turn into a struggle over competing interests, resulting in circumstances that would appear to be the very antithesis of the situation envisaged by the UK government when it sought to establish joint task forces to promote the life sciences industry. The Vioxx-instigated events in the US and the findings of the UK Health Select Committee around the same time both highlighted the unresolved tensions in the expectations that, through new governance approaches, policy-makers will simultaneously be able to:

- engage with a wider range of stakeholders
- increasingly base their decisions on evidence
- and be able to reconcile conflicting views of that evidence in order to deliver both greater transparency and understanding of new technologies to the wider public as well as greater accountability of the main commercial producers and users of those technologies

## A CHALLENGE FOR THE FUTURE GOVERNANCE OF GENOMICS

It has been suggested that technological change may negate old policy instruments and lead to the application of new ones and in many other policy arenas we may indeed have seen a shift from tools of command and control to tools of negotiation and persuasion. But it is generally the case that the political sensitivity of the life sciences, and genomics in particular, requires deterrence rather than self-regulation.

So the challenge for the future governance of genomics involves reconciling the conflicting government priorities of innovation promotion and risk regulation in the life sciences; and reducing frictions between the continuing need for "top down" regulation vs. "bottom up" initiatives that we have seen in participative policy-making.

*Concerns about the role of industry in the development of policy and regulation may lead to greater questioning of the involvement of certain stakeholders in these increasingly participative forms of governance, in particular to avoid what may be seen as privileged access or regulatory capture*

*The challenge for the future governance of genomics is to incorporate the most useful aspects of governance-based approaches and reconcile them with the still necessary systems of regulation in a way that gives all key stakeholders – including the pharmaceutical industry – an appropriate role in the policy debate.*

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## THE LIMITS TO GOVERNANCE

Much of the policy literature tends to assume that governance takes place without government, but the cases outlined here (and discussed in more depth in Lyall 2007)<sup>6</sup> demonstrate the limits to governance and point instead to the notion of a government-governance continuum (rather than a new tool of governance) where different aspects of genomics and life science technologies sit at different points on this continuum; contrasting, for example, the role of the state in controlling and framing the context for the implementation of innovations in life sciences through the regulatory system with the more participative forms of policy-making that are being fostered both to promote national competitiveness and encourage public acceptance of these new technologies.

Doubtless what we are seeing, despite the political (and academic) rhetoric about new governance approaches, is the enduring capacity of the state to control and also to frame debates about new technology. Greater transparency in clinical trials procedures following the Vioxx incident is unquestionably welcome, but this illustrates, not the “hollowing out” process envisaged by the new governance agenda, but instead greater state control: an old control tool being re-applied rather than a new tool of governance.

This raises questions about how “joined up” it is reasonable to expect policies to be for quite distinct purposes (in the case of the life science industries, regulation vs. innovation and promotion) but also raises real practical difficulties when they both involve virtually the same configurations of actors.

The emphasis on networks in the governance literature tends to ignore the continued importance of hierarchy. But in the case of genomics much of the current regulation reinforces this hierarchy and may, in turn, undermine networking processes.

If viable governance systems do indeed depend on dialogue, the involvement of a requisite variety of institutions, and the prevention of institutional polarisation, then there is an inherent danger in any backlash that results in the pendulum swinging too far in the opposite direction away from industry engagement in policy-making solely in favour of public engagement. As with most things, it is a matter of getting the balance right.

## NOTES

<sup>1</sup> The origins of this note lie in a workshop that Innogen ran at the ESRC Genomics Policy and Research Forum as part of the Innogen project on national and international policy regimes for genomics. The author would like to acknowledge the role that the contributors to that workshop played in helping to develop these ideas which have now been published as a journal article (Lyall 2007).

<sup>2</sup> Lyall, C. and Tait J. (Eds) (2005). *New Modes of Governance. Developing and Integrated Policy Approach to Science, Technology, Risk and the Environment*, Aldershot, Ashgate.

<sup>3</sup> Greenaway, J., Salter, B. and Hart, S. (2007), “How policy networks can damage democratic health: a case study in the government of governance”, *Public Administration*, 85(3): 717-738.

<sup>4</sup> Newman, J. (2001), *Modernising Governance. New Labour, Policy and Society* (London, Sage)

<sup>5</sup> Taylor, A. (2000), “Hollowing out or filling in? Taskforces and the management of cross-cutting issues in British government”, *British Journal of Politics and International Relations*, 2:46-71.

<sup>6</sup> Lyall, C. (2007), “Governing genomics: new governance tools for new technologies?”, *TASM*, 19(3):369-386.

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