

Foreword

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This volume is an important component of the output from the first phase of the ESRC Innogen Centre. It builds on the concepts and insights developed for an earlier volume, *New Modes of Governance*,¹ and extends these insights more specifically than before into the life science area. It brings together many aspects of our interdisciplinary research programme which integrates three key research constituencies:

- scientists, medical professionals and industry managers developing life science research and technology;
- policy makers and regulators, involved either in promoting science and innovation or in regulating its products; and
- citizens' and advocacy groups with concerns, either positive or negative, about the implications of the technology.

While each of these three constituencies is considered to a greater or lesser extent in the discussion of principles, processes and people that follows, the book's primary focus is on the second of these groups: policy makers and regulators. Their role is changing in response to fast-evolving life science research, the new knowledge that it is generating and the new development opportunities it presents. From scientists in universities, who are trying to generate new knowledge or who want to see that knowledge translated into useful (and often profitable) products, to multinational companies looking to stock existing pipelines with viable new products or even to generate new pipelines, regulation looms large on their horizons. This is the *government* component of the relationship. However, the *governance* aspects of relationships among the three constituencies outlined above are also important for all involved in life science developments. Increasingly, the actual outcomes of the huge public and private investments in basic science are moderated by the attitudes, values and interests of a wide range of citizens and their representative groups, from NGOs to industry lobby groups and their roles in the governance of the life sciences are also discussed in the chapters that follow.

This book builds a series of interdisciplinary analyses on the basis of ideas and perspectives from social science disciplines that have led recent thinking on

1 Lyall, C. and Tait, J. (2005) (eds) *New Modes of Governance. Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment* (Aldershot: Ashgate).

new governance agendas. However, these agendas have been developed mainly in non-life science contexts; the first phase of the ESRC Innogen Centre's research from 2002–2007 has shown that such insights can rarely be translated simplistically over to life sciences. The overlapping government/governance trajectory acquires new degrees of complexity in a scientific and industry context where the regulatory time-scale is greater than 10 years, costs more than \$500 million, where market choices are usually not made by individual citizens, and where the nature of the science, itself, along with the products to which it gives rise are often publicly contentious.

This complexity indeed raises questions about the value and appropriateness of different models of the government/governance relationship where the shift towards more governance-based approaches in the latter part of the twentieth century can be seen as the accretion of new forms of oversight to an industry sector that was already bearing a heavy regulatory burden. The governance-based approach was promoted in a spirit of optimism as a means to achieve more democratic and more robust political processes and decisions, distributing power more equitably across societal groups. However, in many of the cases described here, the outcome has been greater complexity which has acted to create a different sort of democratic deficit – a shift in the locus of the power base without a corresponding improvement in the responsibility with which that power is exercised.

Government, in the form of regulation, is usually recognized as one factor among the many that combine to determine which products are developed, which companies are able to develop them and generate profits, and even which countries are able to support such profitable industries. Given its function to ensure that products are safe and effective, regulation has always been part of the background in economic and other analyses – a relatively static, non-variant component to be factored in to the overall equation. However, another strand of Innogen's research programme has identified regulation, along with the increasing governance overlay, as *the key* factor determining the shape, location and profitability of research and development activity in the life sciences.

Thus, whether we see the government/governance relationship as a hypothetical continuum as posited at the start of the book or as a more complex model of synchrony, we have by no means solved all of the problems that this new mode of governance set out to address, nor have we avoided creating some new ones. This examination of what limits the success of policy-making is a very timely development, addressing the continuing need for much more creative approaches by the social sciences to the governance challenges raised by the life sciences in developed and developing countries. The ESRC Innogen Centre's Phase 2 research programme to 2012 is focusing on the future governance of the life sciences themselves and of associated opportunities, including the need for constructive change in the governance, government and regulatory approaches to meet the needs of future innovation in areas such as synthetic biology and stem cell therapies, as well as ongoing developments in pharmaceutical innovation.