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**What governs governance, and how does it evolve? The  
sociology of governance-in-action**

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# **What governs governance, and how does it evolve?**

## **Hegemony, consent and the sociology of governance-in-action**

### **Abstract**

Governance addresses a wide range of issues including social, economic and political continuity, security and integrity, individual and collective safety and the liberty and rights to self-actualization of citizens. Questions to be answered include how governance can be achieved and sustained within a social context imbued with cultural values and in which power is distributed unevenly and dynamically, and how governance impacts on individuals and institutions. Drawing on Gramscian notions of hegemony and consent, and recent political science literatures on regulation and meta-regulation, this paper develops a sociological model of governance that emphasizes a dynamic and responsive governance in action. Empirical data from a study of pharmaceutical governance is used to show how multiple institutions and actors are involved in sustaining effective governance. The model addresses issues of how governance is sustained in the face of change, why governance of practices varies from setting to setting, and how governance is achieved without legislation.

Keywords: governance; Gramsci; hegemony; pharmaceutical; regulation; technology

## Introduction

The governance of daily life poses both practical challenges and theoretical questions about balances between the rights, concerns and values of individuals, the state, commerce, professions and other groupings (Hyatt 1997; Jessop 1997: 40; Rosenau 1995: 15). Governance addresses a wide range of issues including economic and political stability, continuity, security and cultural integrity, and individual and collective safety, within a broader context of the liberty and rights to self-actualization of citizens (Loader 1997: 12; Shore and Wright 1997: 30-1). From a sociological perspective, questions to be answered include how governance can be achieved and sustained within a social context imbued with cultural values and in which power is distributed unevenly and dynamically, how governance impacts on individuals and institutions, and how they thus contribute to shaping social organization. We also need to know where and when objects and practices become subjects for governance, how governance varies and adapts over time, and what this tells us about social organization, conflict, resistance and ideology.

Social change and technological developments challenge law- and policy-makers and professionals to weigh a range of contradictory pressures. These include the state's responsibility for the safety of citizens and wider society; democratic rights and freedoms; entrepreneurial efforts to exploit technological advances for the benefit of future citizens; cultural sensibilities and values; economic and political objectives associated with technological development and national prestige. It is the task of effective governance to balance these contradictory pressures and values.

Consequently, exploring governance can give insight into the distribution of power and the dynamics of the processes whereby control over a practice or technology is sustained (Gandy 2003; Rose 2001: 7).

In this paper we shall argue that *consent* is central to how governance succeeds in balancing rival and contradictory dynamics in civil society.<sup>1</sup> Our ideas derive from a problem we faced when trying to make sense sociologically of the governance of pharmaceutical consumption (Fox, Ward and O'Rourke 2005, 2006). None of the existing theories of governance seemed adequate to explain the processes we

observed as stakeholders - including UK regulatory authorities - grappled with changes in access to prescription drugs facilitated by the Internet and web pharmacy. Governance seemed adaptive in character, not fixed in statutes but responsive to changes in the environment and the relative authority of different institutions and actors, including consumers. Back-door deals were done to adapt regulation to meet new circumstances all without recourse to legislation. We were led to develop a model of *governance in action*, based on achieving broad consent within society for regulation and control of consumption.

In this paper we will question how governance and regulation evolve, adapt and change over time. Why, for example, has the governance regime surrounding some technologies and other social practices tended to liberalize (for example, new reproductive technologies from contraception to embryonic stem cell research, homosexual behaviour and rights, and the consumption of soft drugs), while -- especially in relation to health and environmental risks (Backstrand 2004), or marginal social practices -- regulation has become restrictive over time (for example, over genetically modified organisms, smoking in public, paedophilia and so forth)? Both liberalizations and restrictions pose challenges for a theory of governance, which needs to be able to account for such movements. What roles do actors and institutions play in this evolution?

To explore these issues and develop a sociological model of governance, we look first at three ways in which sociologists have sought to understand governance, principally in relation to scientific and technological innovation, before considering a consent model of governance that offers a dynamic approach to understanding authority, consent and resistance. We then discuss this consent model in relation to our data on the governance of pharmaceutical consumption.

## **Sociological approaches to governance**

Governance can be defined as the guidance or control of an activity, in order to meet a specified objective (Jewson and MacGregor 1997: 6; Rosenau 1997: 146). For

regional, national or international governments, governance describes the accountability processes used to shape economic and social activity, and may involve legislation and regulatory processes to set standards, monitor and correct defined areas of activity (Salter and Jones 2002: 810). However, it has been argued that governance cannot simply be reduced to legislation and regulation. In contrast both to unregulated market exchange or centralized, top-down control of people or resources, governance addresses the co-ordination of independent actors involved in

complex relations of reciprocal interdependence ... based on continuing dialogue and resource-sharing to develop mutually beneficial joint projects and to manage the contradictions and dilemmas inevitably involved in such situations (Jessop 2003: 1).

Writers in political science and administrative law have focused recently on the particular character of governance in civil society, to seek understanding of 'governance without government' (Rhodes 1996; Rosenau 1997): the move away from set-piece legislation towards engagement with multiple institutions within society (Cherney, O'Reilly and Grabosky 2006). Governance increasingly entails decentralisation, inclusivity, engagement with the public and bottom-up constructions of consensus and collaboration (Coglianese 1999; Dorf and Sabel 1998; Freeman 1997). However, while these trends may well mark a move away from command governance, from a sociological viewpoint, more needs to be known about how governance is achieved and sustained, given that in a pluralist society, there remain substantial conflicts of interests, values and commitments. Furthermore, policy-makers must continue to act to ensure public safety and security, and the protection of those without power or influence (Coglianese 1999: 32).

Three broad perspectives within sociology have addressed these issues variously. Interest-based accounts, in which groupings with material stakes influence the shape of governance, and value-based approaches, which assess how governance regimes reflect institutional values and cultural contexts, focus upon the 'macro' level of politics and state regulation. The third perspective, governmentality, by contrast is a

‘micro’ approach that examines the ‘mentalities’ of government and the impact of governance on the subject-positions of those who are governed.

### **Interests model**

Within this perspective, governance and regulation reflect the representation of the material stakes of different interest groups such as industry and commerce, profession, scientists, religious groups and so forth who are active within a social setting. In its simplest form, the model attributes core interests to specific groups over specific issues (Macmillan 2003). Citing Abraham (1995) as an example of this approach, Macmillan (2003: 188) suggests that within the interests perspective, ‘drug manufacturers have a consistent interest in turning profits and, at the very least, the buyers of medicines share an interest in not being harmed by their purchases’. Furthermore, these interests may contradict the beliefs held or claims made by these individuals or groups (Abraham and Reed 2002: 339-40). The extent to which these interests are represented within governance and regulatory processes determine the outcomes of these processes. Thus for example, Abraham and Reed (2002: 361-2) argue that discussions during the 1990s International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, the presence of industry scientists and a lack of public health, professional and consumer involvement resulted in outcomes that favoured a lowering and loosening of standards on pharmaceutical safety. Similarly, Sanz-Menendez and Cruz-Castro (2005) found that a strong academic interest group could block Spanish regional governments from re-orienting their science policies towards business.

The value of the perspective is that it supplies a critical position from which to assess governance and regulation. Interests perspectives suggest that the objectivity of regulation is compromised by its failure to address the interests of the broad range of stakeholders, and the differential powers of individuals and institutions (Macmillan 2003: 188). In a study of pesticide regulation, van Zwanenberg and Millstone (2000: 274) argued that bias arose because the interests of government and industry were so closely aligned, permitting ‘shoddy’ analysis of scientific evidence to inform governance decisions. In a discussion of pharmaceutical regulation in Australia,

Lofgren and de Boer (2004) argue that the pharmaceutical industry draws on ‘unique resources in respect of policy analysis, international coordination, lobbying, and direct access to government’, resources not possessed by those favouring stricter regulation (Lofgren and de Boer 2004: 2405). In contrast, it is argued that by favouring particular interests (typically those of patients, consumers and public health) over those of others (typically industrial and commercial organizations), governance can reduce this bias and be made more appropriate and objective (see for example Abraham and Lewis 2002: 73).

Macmillan (2003) criticizes the interests perspective on a number of counts. First, that interests are simplistically ascribed to individuals or groups, while in practice, ‘identity, ideology, income or any of the other characteristics black-boxed as interests, are always more or less fluid’ and may fluctuate from moment to moment depending upon the point at issue (Macmillan 2003: 189). Second, that groups’ interests may actually be much more fragmented than assumed. Third, and concomitantly, that outcomes of governance will rarely simply serve the interests of an entire grouping, so that allegations of bias will tend to discount the contradictory pressures within a pre-existing grouping (Macmillan: 190). To these we would add that this approach may mask the complexity of engagements that occur during the on-going governance of practices, over-emphasising high profile players, typically business and industry. While offering a radical agenda for re-engineering governance, the analysis is sometimes simplistic and deterministic.

### **Institutional structures and values**

The second perspective contrasts with the interests model by emphasizing structural factors that determine the shape of governance outcomes. In the weaker of two models within this perspective, the structures of government determine which arguments are influential within regulatory processes. Organizations are ‘shaped by the culmination of historical forces upon them and embody a distinctive set of structures, ideologies, and values’ (Wiktorowicz 2003: 618). Governments shape the ways in which interests exert influence, and control the impact of interest groups.



Wiktorowicz's study of pharmaceutical regulation in France, Britain and the US contrasts a 'corporatist tradition of negotiation and accommodation with industry' in Europe with industry access to government in the USA limited to judicial appeal. Salter and Jones (2002) make similar points about the impact of institutional organization in relation to biotechnology innovation in Europe. The European Group on Ethics in Science and New Technologies, they suggest, has become a key player in the formulation of policy and regulation of new genetic technologies (Salter and Jones 2002: 812-3). There is, however, little engagement between this formalized bioethics organization and the ethical perspectives of ordinary citizens (Salter and Jones 2002: 813). In a separate study of genetics governance in the UK, Salter and Jones (2006) concluded that the closed and elitist structures and culture of the Whitehall policy community prevent engagement by outsiders, despite a relatively open periphery comprising the Human Genetics Commission and its associated agencies.

Banchoff's (2005) analysis of the contrasting UK and German regulatory frameworks for stem cell research postulates a stronger version of this perspective. He suggests that the historical legacies inherent within institutions shape policy trajectories in three ways: first, by determining who has the power to set agendas and participate in subsequent struggles; second, by creating powerful state apparatuses with investments in sustaining the status quo, and third, by shaping the terms of legislative debate, narrowing the options considered and producing a consequent bias in favour of incremental rather than radical policy change (Banchoff 2005: 207). Thus the UK's centralized constitutional framework, parliamentary legislative sovereignty and majority government enabled the Prime Minister to set an agenda for legislative debate and policy development on embryonic stem cell research and determine which actors should be heard (Banchoff 2005: 212-3), leading to the establishment of a liberal regulatory regime on stem cell research. In contrast, a restrictive German regulatory framework emerged as a consequence of de-centralised government, coalition politics and a constitution enshrining human rights, and together empowered ethical and religious values opposed to research on human embryos (Banchoff 2005: 220-226).

This model provides a more sophisticated understanding of how value perspectives in the institutions of government influence emergent policy and regulation, by suggesting that historical legacies affect how the voices of actors are heard. However, the analysis does not work well when institutions are fragmented or there is no established policy framework (Banchoff 2005: 230). It also becomes hard to explain the changes in regulation that take place over time, because of the emphasis upon continuity within structures and legacies. Like the interests model, it may offer overly simplistic and deterministic explanations that over-emphasise formal regulation and policy-making, ignore the many engagements that occur during on-going governance, including the role of self-regulation, and discount the need for pluralism in civil society.

### **Governmentality**

A further sociological perspective on governance has a contrasting tradition that in many ways differs in its objectives. Governmentality scholars trace their analysis to the work of Foucault and the relationships between power, knowledge and subjectivity. They argue that the central issue for both modern citizens and social theorists is the 'conduct of conduct': how reflexive systems of knowledge shape and affect people's behaviour, subjectivity and understanding of how to live a 'moral' life, according to systems of thought within their society. Governmentality produces modern citizens who live, eat and breath according to these precepts. These are not simply the laws or the policies of governments: Petersen (2003: 192) argues that the techniques and technologies of rule 'are various and differentiated, and operate largely beyond the state'. Citizens actively engage with these techniques of rule, and effectively govern themselves (Petersen 2003, Rose and Miller 1992: 174).

Because of this focus on the relationship between power and self-regulation and self-management, governmentality studies examine the subjectivities forged by the disciplinary regimes that govern how people should behave. In such areas as the emergence of community action, public health emphases on healthy living, child protection and environmentalism, policy can be understood as the conduct of conduct, setting out guidelines on what it means to be an ethical citizen (Herbert-Cheshire

2000; Higgins 2001; Petersen 1997; Schofield 2002). Governance is grounded in a range of rationalities, techniques and organizational forms that seek to govern not through government and legislation but through the regulated choices made by autonomous citizens (Petersen 2003).

Governance within this kind of disciplinary mode of power creates frameworks 'in which individuals "voluntarily" regulate their own conduct in relation to given norms' (Barnett 1999: 372), in particular, those aspects of conduct that are regarded as the basis for democratic citizenship. Rose and Miller suggest that in a disciplinary society, control and regulation

is not so much a matter of imposing constraints upon citizens as of 'making up' citizens capable of bearing a kind of regulated freedom. Personal autonomy is not the antithesis of political power, but a key term in its exercise, the more so because most individuals are not merely the subjects of power but play a part in its operations (Rose and Miller 1992: 174).

This perspective is uninterested in governments and regulatory authorities; indeed Rose (1999) has argued that the emergence of modern societies and economies can and should be understood as governmentality, and that theorists of political and social organization need to re-think their objects of analysis. However, Marinetto (2003: 110) criticizes the perspective for intentionally neglecting the concrete activities of government and the state, reducing politics to issues of mentalities of rule. Governmentality theory may also be criticised for over-emphasising the coherence and univocality of regimes of power in societies (Barnett 1999: 390; O'Malley, Weir and Shearing 1997), while overlooking resistance (Kerr 1998: 193). Nor does this Foucauldian epistemology cope well with diachronic change: changes in governance over time can only be explained in terms of discontinuity rather than continuities, while the role of agency in bringing about change is unclear (Fox 1998: 426-7).

These three perspectives articulate with key themes in sociology: power, interests, values and subjectivities. Each offers interesting insights into aspects of governance, and draw out different features. Interests theories point to the vested power of certain groups and the uneven influences over policies and technologies that favour business and industry in capitalist societies, while the institutional structures theory recognizes that cultural values may be imbued within governmental institutions, replicating the biases towards particular policies. Both theories, however, are weak when addressing the fluid character of governance that has been identified empirically.

Governmentality theory introduces the importance of self-regulation and the reflexivity within governance regimes that leads citizens to adopt particular behaviours and commitments. While of interest in exploring the de-centralisation of governance in civil society, it is limited as a perspective when seeking to understand questions of how governance is managed by states and other governmental organizations in the face of social, political or technological changes, and the motifs for changes to regulation.

Faced with empirical data from a study of pharmaceutical governance (Fox, Ward and O'Rourke 2005, 2006), we found that none of these angles adequately explained the mutability and flexibility of modern governance of technology, what might be called *governance in action*. We felt that all were wanting when addressing a number of critical questions concerning governance, and that these raise questions that a sociology of governance would wish to answer:

- Why do governance and regulation change over time, and from setting to setting (e.g. internationally)?
- In addition to powerful interests, are the commitments and values of the general populace accounted for within governance? If so, how are these incorporated?
- Is legislation or formal regulation necessary for governance?

Later in the paper we consider the data from our study, and examine these issues in more detail. First, in order to begin to address these key questions, we wish to foreground an aspect of governance that has been raised in some political science literatures but is not fully addressed by any of the three perspectives outlined thus far.

## **Governance and the problem of consent**

In civil society, a central problem for government in formulating policy to serve economic, social, cultural and ethical objectives (for example on economic growth, crime, environmentalism or public safety) is how to achieve and sustain broad consent from citizens in the context of potentially plural and conflicting interests and values. This problem, whose resonances hark back to an earlier era and the reflections of Antonio Gramsci on the building of hegemony in bourgeois society, requires a dialectical analysis of the art of government. Hegemony for Gramsci was contingent and unstable, reflecting the contradictions and fault-lines within society. To govern effectively requires attention to the fluctuating balances of power in a social field (Gramsci 1971: 181-2): government entails on-going work to achieve and sustain consent between powerful, antagonistic groups within a society. Lose the consent of the populace and hegemony evaporates. For Gramsci, this explained the surprising capacity of capitalism to defuse the objective economic antagonism of the proletariat through mobilisation of consensual values and beliefs (including nationalism) and on-going political manoeuvring.

Levy and Egan (2003: 809) suggest that Gramscian processes of negotiation, alliance formation, and compromise can be seen in a range of contemporary civil society settings from international trade to conflicts over the welfare state. Coglianese (1999) notes that consensus-building is an integral element in US regulation, while public consultation has an increasing role in government (Gramberger 2001). Rosenau (1995, 1997) argues that effective global governance requires recognition of multiple 'sources of authority', each with varying and potentially contradictory material and ideological stakes that bear upon a particular activity, practice or technology. Often formal legislation is inappropriate or unfeasible, and regulation of an activity depends not so much upon the naked exercise of power but through the steady accretion of consent around a value, norm or standard (Rosenau 1992). Governance becomes possible when those (a government, a profession, a social movement or group) who seek control over an activity achieve consent from those who are to be controlled, thereby establishing a *system of rule* that regularizes activity. For a successful system

of rule, voluntaristic, consensual and collaborative interactions are more important than legal or political authority (Rosenau 1997: 147). Professional associations offer an exemplar of the self-regulatory character of governance: here members consent to be governed in return for the benefits of collegiality, independence and societal respect and prestige.

This latter approach presents governance as a dynamic, dialectical process, a deployment of a system of rule by social actors that is never fully achieved, but once established is reasonably resistant, as it draws on a broad base of consent from those involved, be they citizens, consumers or members of an organization or constituency. Thus, for example, Hysing and Olsson (2005) found that policy-makers gained consent from forest-owners to support a policy of biodiversity by a mix of voluntary agreement around certain principles, even though the owners' underlying values and interests stood in contrast to this policy. We are reminded too of the failure of Thatcher's UK poll tax, a policy that never achieved popular consent, being perceived as contrary to fundamental (British) notions of individual liberty and fairness. This flagship policy was overturned despite a large parliamentary majority, a loyal civil service and a weak opposition (Butler, Adonis and Travers 1994). The error was not to recognize that the wider citizenry was a significant source of authority in this context.<sup>2</sup>

It is important to note that this analysis is neither a recapitulation of an interests model, nor simply a reduction of governance to a process of consensus and lowest-common-denominator policy-making. In the interests approach, policy, regulation and legislation emerge during processes of consultation, in which powerful interests (usually those congruent with those of the state or government) overwhelm those of the less powerful (usually the citizenry). Notions of collaborative governance move to an opposite extreme, promoting broad participation, joint problem-solving by stakeholders, sharing of responsibility by public and private agencies (Freeman 1997), and ultimately a degree of 'fudge' that blurs disagreement (Coglianese 1999: 25). In the model outlined here, the possibility of policy and regulation is predicated upon the need to forge broad *consent* among *antagonistic* sources of authority. These sources

of authority are grounded in a variety of cultural, political, economic and organizational power-bases, and for any source of authority a particular practice or technology may throw up contradictory interests. The art of governance is to exploit these conflicts, manage alliances and trade-off costs and benefits, always with one eye upon 'public opinion'.

Nor does this approach reduce governance to an abstract exercise of power, as in governmentality theory. Governance is pursued by social actors with concrete objectives around economic prosperity, public safety, social equity and so forth. In pursuit of these objectives, they aim to accommodate differences, exploit underlying social and cultural values and minimise future challenges to legislation or regulation. Government is pragmatic, aimed at enabling social activity to proceed within the wider objectives of civil society and the political and economic agendas of the region, nation or supra-national polity. The success of legislation will depend upon broad consent from sources of authority, and laws failing to achieve this consent will not survive. Regimes of governance emerge around those areas of social life or technological developments that have wider cultural, social or political ramifications, while those without such contexts do not operate in a contested field, and are governmentally non-problematic.

There are various sociological consequences that derive from this dynamic model of governance. First, governance is not the starting point for control of an activity but the outcome of a series of explicit or implicit engagements with a multiplicity of social actors and collectivities that have stakes in the activity. Achieving consent is not a bureaucratic exercise but an active process aiming to achieve consent from these actors and collectivities. Second, within the multiple institutions of civil society, sources of authority continuously vie for control, forming coalitions that range from the relatively stable to *ad hoc* alliances that circumvent traditional sources of authority (Rosenau 1997: 171-2). These coalitions are grounded in shared values, but are often contingent and partial. Finally, social, political, economic or technological changes in the environment can increase or reduce the power of one or another source of authority in a field. In response, governance must adapt or risk being weakened or

failing (Rosenau 1995: 17-18; Rosenau 1997: 152; Cashore 2002). We may track the shaping of governance empirically as it responds to social and other change, as we will now demonstrate.

### **Pharmaceutical consumption and the internet: a case study of governance in action**

We turn now to a case study of governance that considers the importance of consent for the successful deployment of regulation, in the face of an environmental change that potentially de-stabilizes the balances between sources of authority. The case in point concerned changes that have occurred in the regulation of pharmaceutical consumption in the UK following the emergence of the Internet as a medium for commerce.<sup>3</sup> During this research, we used documentary analysis and interviews with regulators, consumers, industry, commerce and pharmacy professionals, to explore how governance and regulation had adapted to meet the changing circumstances surrounding pharmaceutical consumption facilitated by the Web (Fox, Ward and O'Rourke 2005, 2006).

Enabled by Internet technology, web pharmacies<sup>4</sup> now sell a range of pharmaceutical compounds to the public, including pharmacy medicines (PMs) dispensed by licensed pharmacists and prescription-only medicines (POMs) that require the signature of an accredited prescriber. UK citizens may legally purchase and import these drugs (apart from controlled substances) for personal use, and many overseas web-based pharmacies market to UK consumers, subject only to the laws of their host country. This trans-national market in pharmaceuticals challenges national governance regimes that have developed to regulate how pharmaceuticals may be marketed and sold. Conducted while these trends were becoming established in the UK in the early 2000s, our study found that the UK regulator, the Medicines and Healthcare Products Regulatory Authority (MHRA), worked with consumer groups, professional bodies and industry to agree three subtle changes to existing governance of pharmaceutical marketing and consumption, in response to the emergence of web pharmacy. Significantly, these changes were made without any alterations to legislation.



The first of these changes enabled a PM to be legitimately purchased from a UK-based web pharmacy, so long as a registered pharmacist assesses patient suitability via an online questionnaire. This change was facilitated by a change to the code of conduct of the pharmacy profession's professional association, the Royal Pharmaceutical Society of Great Britain (RPSGB). They argued that a 'remote patient' was not new or unique: pharmacists were often required to dispense medicines to family and friends on a patient's behalf, and this way of working could be replicated online using questionnaires and emailed advice as modes of communication. Many aspects of web pharmacy such as compliance with marketing regulations, provision of drug information, record keeping and accountability could translate directly from traditional to online environments (Appelbe and Wingfield 2001).

The second change permitted POMs to be sold by UK web pharmacies and clinics, so long as there was a prior online consultation with a licensed prescriber. Legislation enshrined in the UK's Medicines Act 1968 requires POMs to be obtained only by valid prescription, while a European Commission states that patients must have 'meaningful contact with a qualified medical professional' before prescription (Muscardini 2001: 57). In discussion with a handful of putative online clinics wishing to sell POMs to UK consumers, the MHRA agreed in 2003 that 'online consultations' could achieve this definition of contact

... there is no requirement under medicines legislation for this to be face-to-face. Therefore, there is nothing to prevent a doctor prescribing or supplying a medicine on the basis of, for example, an on-line questionnaire. That said, we would take the view that it should contain sufficient information for the doctor to make a decision about whether or not any proposed treatment was appropriate (interview with MHRA representative)

A third change concerning marketing of POMs by web pharmacies posed the greatest challenge to the MHRA. Legislation (the Medicines (Advertising) Regulations 1994

and European Directive 2001/83/EC) strictly prevents any direct advertising of POMs to UK consumers. British web pharmacies must compete with US counterparts, which are allowed by their laws to promote a wide range of available products direct to consumers. We learnt that the agreement described above between the UK regulator and British web pharmacies required that their websites detailed only the conditions that the clinic treated, without naming pharmaceuticals that would be sold to those using the clinic. Following a free online consultation with a UK-registered doctor, consumers would only then be e-mailed details of their diagnosis and suggested treatments, and provided with a web address from which to buy the product recommended by the consultant. The regulator's principle was equivalence with a face-to-face consultation

... you would not go to your doctor and say 'I would like Viagra please', instead, you would go and discuss your condition, then the doctor considers the facts before selecting a drug or range of drugs. This principle is one that they feel would need to be replicated and considered acceptable on the web (interview with online clinic director)

What is the significance of these three changes for the regulation of pharmaceutical consumption in the UK? When attempting to understand our data, we were struck initially by the apparently casual response of the regulator to what appeared major challenges (in particular, the online prescribing and dispensing of POMs). Furthermore, there was a substantial degree of behind-closed-doors discussion with industry, professional associations and so forth, leading to new agreements and adaptations to voluntary codes. Finally, the regulator responded to 'consumer power', which underpinned the need to adapt to new market forces and demands. These data suggested that governance cannot be understood simply as a framework of top-down regulation, underpinned by legislation as required. Rather, it is a negotiated and on-going process of *governance in action*, based on the 'continuing dialogue and resource-sharing to develop mutually beneficial joint projects' suggested by Jessop (2003: 1). Indeed, governance might be seen not as exclusive to regulators but

disseminated across the various institutions of civil society, whose consent enables the framework to work effectively.

We can unpack this governance in action process by examining the social actors involved. Figure I illustrates the sources of authority surrounding pharmaceutical consumption, and we may regard these as the actors and institutions whose consent contributes to the on-going governance of pharmaceutical consumption. On the left are those that tend towards tighter control of pharmaceutical consumption, while on the right are those that favour de-regulation (cf. Lofgren and de Boer 2004). The governance of this practice must balance governmental and consumer watchdog concerns over the safety of the public and the pharmacy profession's control of dispensing against the demands of consumers for the right to access pharmaceuticals, and the protection of commercial pharmacy and employment in a global market. Note that pharmacists appear on both sides of the field: such conflicts of interests are not uncommon and remind us of Macmillan's (2003) critique of interest theories of governance.

*Figure I: sources of authority on pharmaceutical consumption*

<b>Restrictive sources of authority</b>	<b>Liberalising sources of authority</b>
Government (responsibility for public health and safety)	Government responsibility to promote UK markets
Pharmacy profession (exclusive rights to dispense pharmaceuticals)	Consumer rights to purchase POMs and PMs for personal use
Consumer watchdog (protection of public from commercial exploitation)	Consumer demand
	Pharmacies (commercial opportunities and competitiveness in global market)
	Pharmacy profession (employment opportunities)
	Pharmaceutical industry (increased markets for lifestyle products)

Effective governance requires that broad consent for policy on pharmaceutical consumption is achieved among these social actors. The emergence of the Internet as a trans-national market for POMs upset this balancing act, strengthening consumer opportunities (and according to our data, willingness) to use their legal rights to acquire and/or import POMs for personal use. The pharmacy profession supported their members' exclusive rights to dispense pharmaceuticals but wished to extend this to cover online pharmacy operations, both to retain control of dispensing and protect jobs. Consumer protection groups regarded online pharmacy as threats to safety from unscrupulous commercial interests. We also found that the pharmaceutical industry tempered its enthusiasm for de-regulation with a fear that online pharmacy would provide a marketplace for bootlegged versions of their patented products (Fox, Ward and O'Rourke 2005). In this context, the three interpretations of the existing system of rule negotiated by the UK regulator make sense:

- By enabling pharmacists to dispense online, their control over dispensing is protected. This both allows UK online pharmacies to compete against foreign businesses and protect pharmacy jobs in the UK, and reduces the likelihood that bootlegged or unsafe products will be sold to UK consumers by overseas web pharmacies.
- Similarly, by confirming that 'online consultations' are adequate for prescription of POMs, web pharmacies and clinics can operate and compete legally and profitably from on-shore premises.
- By requiring consultation to precede any marketing of products, the UK and European law on direct advertising to consumers is not breached, acknowledging powerful public, professional and political concerns with any watering-down of the principle (efforts to allow limited marketing to consumers had been thrown out by the EU Parliament in 2002), while recognising consumer demand for flexible access to POMs.

This analysis suggests that three adaptations to practices succeeded in sustaining broad consent among the sources of authority involved with pharmaceutical consumption, including the emergent UK web pharmacies. Consumers would accept

the constraints on marketing in return for re-assurance that purchases from on-shore web pharmacies would provide the protection of UK consumer law, while the industry would get a new market for their products. A small alteration to the pharmacy profession's code-of-conduct enables UK pharmacy businesses to exploit the opportunities of the Web, with benefits for employment and profitability. All this was achieved well away from the high-profile set pieces of governance. This analysis would suggest that such set pieces (commissions, parliamentary debates, public consultations and so forth) may be less significant for understanding governance than has been suggested by those working in both interests and structuralist perspectives.

## **Discussion**

We have used this case study as empirical evidence of the 'governance in action' that occurs when the environment in which a practice or technology is located changes, altering the balance between sources of authority. We found a process of governance that was dynamic, involving multiple actors and institutions, and aiming for broad consent over how practice should be subject to control. The set-pieces of governance: public enquiries and consultations, legislation and regulatory authority mask the real work of governance that happens much more quietly behind the scenes, as governors work with institutions and actors within a disseminated network of control. Parker (2002) and Morgan (2003) call this 'meta-regulation', whereby regulators act as brokers (Cherney, O'Reilly and Grabosky 2006) to encourage other institutions to self-regulate. Scholars in political science and law see this as a way to address problems such as restorative justice and risk management in civil society (Parker 2002; Braithwaite 2005), but from the perspective of this paper, the significance is that governance is becoming more and more hands-off, as self-regulating institutions such as professional associations and corporations are involved in the state's efforts at control and regulation.

Earlier we identified some critical questions for understanding the social organization of governance, and with the benefit of the case study, we can recognize these as highly inter-related. The first question concerned the empirical observation that governance varies over time and from setting to setting. In our case study, we

observed both a change in the environment (and these may be social, political, economic, cultural or technological in character), and a response that altered the shape of pharmaceutical governance. Studies of regulation of technologies such as embryonic stem cell research demonstrate huge variability in governmental policy, so that, for instance, no research is permitted in Eire while across the border there is one of the most liberal regulatory regimes in the world. We suggest that these differences reflect the realities for effective governance of achieving broad consent across sources of authority in a society. Variations in regulation may reflect deep-seated cultural values in the population (for example, fundamentalist opposition to abortion or the sense that a flat-rate poll tax is unjust and 'un-British'), political and economic orientations (for example, to exploit opportunities as world-leaders in medical research), as well as the strengths of institutions such as professional groups and business. However, governance of these sources of authority must be responsive to changes in the environment that lead to changes of sentiment (for example, the demand for lifestyle POMs in our study, or the groundswell of demand for stem cell research among ageing populations in the USA). This leads neatly to our second question.

We asked whether it was simply powerful values that hold sway in determining policy, or whether the populace's consent is needed for effective governance. Interests perspectives argue that often the concerns of the general public are overlooked because in a capitalist society, powerful interests of business and industry broadly match the economic aspirations of governments, while citizens' interests can be sidelined. The best that can be hoped for is that by exposing governance to democratic principles, it will be made 'fairer'. Various writers have argued that empirically, this is an inaccurate description of civil society (Cherney, O'Reilly and Grabosky 2006; Freeman 1997: 3). They point to moves towards more collaborative approaches, to the centrality of consultation over policy and services, and to de-centralization of regulation (Dorf and Sabel 1998; Freeman 1997; Gramberger 2001). Our case materials support the importance of broad consent for governance, though from a somewhat different, neo-Gramscian angle. The art of governance appears to be to sustain broad consent (and thereby hegemonic power) across the institutions and actors engaging around a practice, but this is achieved not by coercion but by the

dissemination of control to these very institutions and actors. Institutions are encouraged to self-regulate practice through codes of conduct and self-policing, while actors are offered compromises that buy-off dissent and resistance. What governors fear most, it would seem, is that antagonisms erupt, leading to the breakdown of governance as institutions or actors shatter the hegemony. Again, this leads to our next question.

This concerned the importance of legislation and formal regulation for governance. Much sociological exploration of governance has focused on these elements, at the expense of the kinds of governance in action aspects that our case study highlights. Writers such as Rhodes (1996) and Rosenau (1997) by contrast discuss the rise of 'governance without government'. Rosenau argues that governance emerges out of the on-going engagements between those seeking control over an activity and those who to be controlled. The interactions between these groups constitute the system of rule, 'founded on a modicum of regularity, a form of recurrent behavior that systematically links the efforts of controllers to the compliance of controllees' (Rosenau 1997: 14-15). Systems of rule become established in the absence of legal or political authority, and Rosenau's work has explored the emergence of global governance based on voluntaristic, consensual and collaborative systems of rule such as the emergent agreements around climate change or support for developing countries (Rosenau 1997: 147).

The concept of governance as 'brokerage' developed by Cherney et al. (2006) is of value here. They suggest that the role of governors is progressively to connect the capacities of civil society institutions (industry, professional associations and so forth) to govern certain aspects of practice such as crime control. This engagement can be formalised or may rely upon spontaneous engagement by institutions (Cherney, O'Reilly and Grabosky 2006: 379). The progressive routinization of practices such as audit to evaluate performance against objectives (Scott 2003) or reflexive monitoring and accountability in systems such as clinical governance can be seen as exactly this kind of brokerage whereby quality of service is delegated to institutions rather than by government.<sup>5</sup> This analysis offers a different take on the progressive 'reflexivisation'

or ‘responsibilisation’ (Rose 1999) described in governmentality theory as the motors of civil society. In our approach, these institutions are not agencies within an abstract, anonymous, disciplinary power, but consenting participants in the pursuit of specific social, political or economic objectives.

Self-governance, meta-regulation, brokerage and governance without government are thus progressively occupying the agendas of both governments and academics. The emergence of new transnational networks also implies that the nation-state may be limited in future governance (Rosenau 1997; Ronit and Schneider 1999). Consent plays a key role in civil society, and we have outlined how a sociology of governance may be grounded in analysis of consent and dissent. We also have demonstrated that such explorations are open to empirical study, although with a new focus on the meta-regulation activities of governors and the engaged activities of actors and institutions that together shape the activities and practices within civil society. We are interested in the ways in which consent is achieved, the ‘modicum of regularity’ that links social actors into governance, to use Rosenau’s (1997: 14) phrase. These acts of consent can be discovered by fieldwork at the sites of governance in action, among the actors and institutions that comprise the networks of meta-governance.

We chose to focus in this paper on the regulation of web pharmacy because our data could get behind the scenes of governance and explore the processes that are used to tweak frameworks, away from the bright lights of legislative debate and regulatory development. However, the approach developed here can be applied to a range of critical issues in the governance of social activities and technologies. For example, it allows exploration of the actors involved in the rapidly changing national and international governance of energy usage in the face of climate change, from personal transportation choices through to national policy on greenhouse gas emission and energy production and conservation. It can be applied to issues of consent around security and liberty that are emerging for both individuals and states, from street surveillance to citizenship tests. The role of science as a new basis for hegemony in secular society can also be addressed in terms of governance in action. In all these



and other areas, we can explore how social actors and institutions engage with government, and follow the trajectories of governance as it evolves. .

## Notes

1. The term civil society refers to the mix of spaces, actors and institutions that together comprise a non-coercive, democratic society including social, voluntary, community-based, emancipatory, religious and self-regulatory collectivities. Governance in civil societies acknowledge the role of these groups in sustaining social processes.
2. The failure of this policy is sometimes ascribed to ‘group-think’ that led to unrealistic policy-formulation. The analysis here would suggest that it was a consequence of Thatcher’s success in reducing trade union power that blinkered her to the authority of the populace.
3. Economic and Social Research Council project L218252057, funded within the Innovative Health Technologies programme.
4. Sometimes referred to as online pharmacies or e-pharmacies
5. Dorf and Sabel (1998) suggest that benchmarking and monitoring open the way for ‘democratic experimentalism’, in which civil society institutions may pursue ends free from centralised control of means.

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