European Observatory on Health Care Systems Series
Edited by Josep Figueras, Martin McKee, Elias Mossialos and Richard B. Saltman

Regulating entrepreneurial behaviour in European health care systems

Edited by
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European national policy-makers broadly agree on the core objectives that their health care systems should pursue. The list is strikingly straightforward: universal access for all citizens, effective care for better health outcomes, efficient use of resources, high-quality services and responsiveness to patient concerns. It is a formula that resonates across the political spectrum and which, in various, sometimes inventive configurations, has played a role in most recent European national election campaigns.

Yet this clear consensus can only be observed at the abstract policy level. Once decision-makers seek to translate their objectives into the nuts and bolts of health system organization, common principles rapidly devolve into divergent, occasionally contradictory, approaches. This is, of course, not a new phenomenon in the health sector. Different nations, with different histories, cultures and political experiences, have long since constructed quite different institutional arrangements for funding and delivering health care services.

The diversity of health system configurations that has developed in response to broadly common objectives leads quite naturally to questions about the advantages and disadvantages inherent in different arrangements, and which approach is ‘better’ or even ‘best’ given a particular context and set of policy priorities. These concerns have intensified over the last decade as policy-makers have sought to improve health system performance through what has become a European-wide wave of health system reforms. The search for comparative advantage has triggered – in health policy as in clinical medicine – increased attention to its knowledge base, and to the possibility of overcoming at least part of existing institutional divergence through more evidence-based health policy-making.
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The volumes published in the European Observatory series are intended to provide precisely this kind of cross-national health policy analysis. Drawing on an extensive network of experts and policy-makers working in a variety of academic and administrative capacities, these studies seek to synthesize the available evidence on key health sector topics using a systematic methodology. Each volume explores the conceptual background, outcomes and lessons learned about the development of more equitable, more efficient and more effective health care systems in Europe. With this focus, the series seeks to contribute to the evolution of a more evidence-based approach to policy formulation in the health sector. While remaining sensitive to cultural, social and normative differences among countries, the studies explore a range of policy alternatives available for future decision-making. By examining closely both the advantages and disadvantages of different policy approaches, these volumes fulfil a central mandate of the Observatory: to serve as a bridge between pure academic research and the needs of policy-makers, and to stimulate the development of strategic responses suited to the real political world in which health sector reform must be implemented.

The European Observatory on Health Care Systems is a partnership that brings together three international agencies, three national governments, two research institutions and an international non-governmental organization. The partners are as follows: the World Health Organization Regional Office for Europe, which provides the Observatory secretariat; the governments of Greece, Norway and Spain; the European Investment Bank; the Open Society Institute; the World Bank; the London School of Hygiene & Tropical Medicine and the London School of Economics and Political Science.

In addition to the analytical and cross-national comparative studies published in this Open University Press series, the Observatory produces Health Care Systems in Transition Profiles (HiTs) for the countries of Europe, the Observatory Summer School and the Euro Observer newsletter. Further information about Observatory publications and activities can be found on its website at www.observatory.dk.

Josep Figueras, Martin McKee, Elias Mossialos and Richard B. Saltman
Foreword

Policy-makers often find themselves torn between two seemingly contradictory health sector objectives. On the one hand, shifting demography and improving technology generate strong interest in permitting innovative new procedures that can improve the ability of service providers to respond to the needs of patients. On the other hand, insufficiently tested interventions and inadequately thought-through schemes run the risk of damaging patients’ health and perhaps even their chances of survival. Faced with this conflict, many policy-makers feel that the only responsible path is to adopt a strong regulatory regime. Confronted by the unknown in the form of unleashed entrepreneurialism, they prefer the known consequences of static, often bureaucratic models of service design and delivery.

Yet the art of regulating well, as this volume contends, is to develop regulatory strategies and frameworks that pursue a middle path, by allowing the carefully controlled introduction of innovative approaches without surrendering major responsibility for achieving good overall outcomes for patients. It is in this balance, in understanding regulation as a means rather than an end, that the way forward must lie. By developing these new regulatory approaches, and by working with countries as they adapt these methods to their own unique health sector circumstances, international organizations can ensure that policy combines the necessary dynamism that entrepreneurialism brings with the essential stability that good public health policy requires.

Ultimately, regulation should be understood as a major instrument in the pursuit of effective stewardship. For governments to successfully manage their health care systems in the public interest, their regulatory initiatives must
accommodate a range of innovative as well as traditional objectives, and facilitate the introduction of new as well as the operation of existing activities. This fusion of regulation with entrepreneurialism, then, can serve an important role in the development of effective stewardship of the health sector. It is towards this goal that this volume makes a valuable contribution.

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Richard B. Saltman, Reinhard Busse and Elias Mossialos
part one
chapter one

Balancing regulation and entrepreneurialism in Europe’s health sector: theory and practice

Richard B. Saltman and Reinhard Busse

The new regulatory challenge

The 1990s witnessed a dramatic upsurge in the scale, character and calibre of entrepreneurial initiatives within European health care systems. A wide variety of market-inspired efforts to stimulate service innovation, including increased quality and greater efficiency, have been launched in both public and not-for-profit private sectors, and in core health service activities as well as in more peripheral supplies and services. This structural ferment is visible whether one looks to the United Kingdom and the Nordic countries across northern Europe, to Spain, Portugal and Italy in the south, to the Netherlands and Germany in the European heartland or to the pre-accession countries of Central Europe. The upsurge in innovative activities, although not as great as many proponents had hoped, has been far greater than more cynical observers had expected. In practice, the last 10 years have been a period of substantial organizational reconfiguration in the health sector, and increased entrepreneurial activity has been at the core of that process of change (Saltman and Figueras 1997; Saltman et al. 1998; Paton et al. 2000).

This European experience has demonstrated that entrepreneurialism can, in practice, be a powerful lever to induce institutional restructuring in the health sector. Entrepreneurial behaviour has long been recognized as the central catalytic element in stimulating industrial innovation, defined as the process of identifying, developing, introducing and commercializing a new product or service. The most economically pure definition of an entrepreneur is attributed to the
early nineteenth-century French economist Say, as someone who ‘shifts economic resources out of an area of lower and into an area of higher productivity and greater yield’ (Drucker 1985: 21). Nearly a century later, the German economist Schumpeter understood entrepreneurialism as inextricably tied to the waxing and waning of major business cycles, each tied to new technologies and the new industries that grew up around them (Schumpeter 1911). The role of an entrepreneur was to take advantage of a broad opportunity for structural change by introducing a ‘dynamic dis-equilibrium’, signalled by ‘creative destruction’, that could push a national economy forward to new levels of efficiency and performance. Reflecting the same central logic but from the level of the individual firm, Hamel and Prahalad (1994) view entrepreneurial behaviour not simply as developing a new product but conceptualizing and bringing into being whole new markets that never before existed (for example, Sony with the development of the video camera in the 1980s). Entrepreneurs, in this analysis, compete not for market share or profit alone, but for a more essential precursor: ‘to shape the structure of future industries’ (Hamel and Prahalad 1994: 25). Drucker (1985: 28) summarizes the optimistic view of entrepreneurialism’s proponents by defining an entrepreneur as someone who ‘searches for change, responds to it, and exploits it as an opportunity’.

Those who seek to apply the lessons of entrepreneurialism to the not-for-profit private and the public sectors adopt a similar logic, although they have a decidedly different focus on the objectives of entrepreneurial behaviour. Dees suggests that social entrepreneurship ‘combines the passion of a social mission with the image of business-like discipline, innovation and determination’ (Hunt 2000: 27). van der Grinten (1999) explores the concept of social entrepreneurialism, involving innovative services in not-for-profit Dutch hospitals and home care. The logic of social entrepreneurship draws upon Hood (1991), who has written more generically about the importance of freeing senior civil servants to perform much the same function as private sector entrepreneurs in the implementation of innovative social sector policies. Looking at the opposite end of the public sector hierarchy, Lipsky’s (1980) classic study of ‘street level bureaucrats’ demonstrated that entrepreneurial innovation could often be found among front-line personnel working directly with individual clients. Hunter (1997) highlights the potential in the health sector to supplement traditional bureaucratic requirements with the managerial autonomy that forms an important component of Hood’s New Public Management School. Drucker (1985: 254) concluded his own analysis by arguing that innovation and entrepreneurship are needed ‘in society as much as in the economy, in public-service institutions as much as in business’.

This conceptual and practical emphasis on entrepreneurialism can have a positive impact on health systems when the changes undertaken help strengthen the ability of national policy-makers to achieve their stated policy objectives. At the organizational level, entrepreneurialism seeks to modernize and rationalize organizations to increase their operating efficiency. In the private sector, the surrogate symbols for efficiency are, typically, increased profits as well as expanded market share and, in some industries, improved quality of product and service to customers. In the public sector, the surrogate symbols are improved volume and quality of service to clients, as well as generating a
Balancing regulation and entrepreneurialism

financial surplus and, in some sub-sectors, enhanced market share. Increased efficiency is also seen as essential to preserving the range and scope of current benefits offered by the public sector to the citizenry.

At the societal level, some economists view entrepreneurialism as important because they believe that it necessarily expands the choice of products or services available to individuals (Rice 1998). Expanded choice can also be a valuable outcome of innovation in publicly operated health systems (Saltman and von Otter 1992). Public sector planners, somewhat differently, tend to emphasize the macro-level advantages of entrepreneurialism in achieving a better match between resources invested and output obtained, what is sometimes termed ‘better value for money’ (Smee 1995).

The powerful impetus to innovate generated by entrepreneurialism can have decidedly less positive effects, however, when it has not been adequately fenced in by effective state regulation. Entrepreneurs inevitably seek to segment markets so as to exploit profitable niches, while publicly accountable regulators try to ensure that the entire market is served efficiently and affordably. The potential scope for dysfunctional outcomes from unconstrained entrepreneurialism in the health sector is vast. At the extremes, it ranges on the funding side of health care systems from bankrupt insurance companies (Czech Republic, Slovakia) and massive deficit spending (Hungary, Estonia) to efforts to design service baskets that chase away undesirable (i.e. more expensive) subscribers (Netherlands) (de Roo 1995). As Sheiman and Wasem stress in Chapter 9, central and eastern European countries have learned to their chagrin that, with regard to health insurance, there is real danger in instituting new entrepreneurial mechanisms without adequate regulatory support. On the provider and production side of health systems, inadequate regulatory frameworks have been unable to restrain incompetent surgeons who operate despite regularly fatal results (paediatric surgeon in Bristol, United Kingdom), independent pharmacists who sell powerful drugs without prescriptions (Spain), private clinical laboratories that falsify test results (Sweden) or unscrupulous drug companies that dump out-of-date stock on unsuspecting patients (former Soviet Republics).

Precisely to preclude such outcomes, the scope of the regulatory apparatus that national policy-makers put in place to safeguard national policy objectives tends to be comprehensive and complex. It incorporates a wide variety of mechanisms, from legislative acts to administratively imposed reporting requirements, and from positive incentives such as subsidies to negative incentives such as legal sanctions. The unique character of health care as a social as well as a private good reinforces the importance of the regulatory role in the health sector (Saltman in press). Yet regulation is an essential element in harnessing entrepreneurialism within all sectors of a modern economy. Consumer-related industries in much of Europe operate under an extraordinary range of legislative, legal, product safety, sales, marketing, employer, occupational safety, environmental, financial, tax, construction and other regulatory responsibilities. The threat of anti-competitive rulings by the European Commission to halt potentially monopolistic mergers demonstrates that even the largest and wealthiest private sector corporations operate their businesses subject to regulatory supervision by the state. In practice, some of the more extravagant arguments in favour of deregulation need to be judged in the context of the extensive scope
Regulating entrepreneurial behaviour of existing state regulatory authority. Such an assessment suggests that even major deregulatory efforts would leave (and undoubtedly should leave) a wide-ranging body of other regulatory measures still intact. As elsewhere in the economy, in the health sector – indeed, especially in the health sector given the social character of its operating objectives – the strength of entrepreneurial incentives makes it essential to have in place adequate regulation to ‘steer-and-channel’ what would otherwise be only self-interested private decisions.

This concern with the social importance of regulation can serve as a useful introduction to recent experience with state regulation of entrepreneurial behaviour in European health systems during the 1990s. The most basic observation one can make about this activity is that a substantial volume of new regulation has been generated over the course of the decade. Largely in response to the needs of both intentionally and unintentionally generated entrepreneurial activities, most European countries established new types, as well as expanded the existing range, of what can be termed steer-and-channel regulation. In the United Kingdom, for example, the introduction of the purchaser-provider split, of self-governing trusts and of general practitioner fundholders, all required large new regulatory initiatives, which are currently being evaluated for consistency and coherence by the Department of Health (C.H. Smee, personal communication). In Germany, the introduction of individual choice among sickness funds, as well as the introduction of global budgets for hospitals and other cost-control measures, similarly expanded the regulatory apparatus of the state. Parallel patterns could be observed in the Netherlands, Spain, Italy and the Nordic countries. Moreover, these regulatory efforts constantly evolved over the course of the decade to meet new concerns, to reflect developments in the health sector and to reflect changes in policy due to changes in sitting governments.

Thus, as areas of entrepreneurial activity grew, they were accompanied by a parallel growth in related state regulation. As has been suggested elsewhere (Saltman 1997; Saltman and Figueras 1997), increased reliance in Western European countries on markets to make production-related decisions in the health sector has necessarily been accompanied by an increased (if more outcome-rather than input-oriented) role for the state. Precisely because the state is now expected to ‘row less but steer more’, its role in driving the health sector forward has in practice had to increase in scale, scope and sophistication. Indeed, the state’s supervisory responsibilities have evolved to the point that the term ‘stewardship’ has now been applied to its overall policy and management obligations in the health sector (Saltman and Ferrouster-Davis 2000; WHO 2000). Drawn from religious and environmental roots, the concept of stewardship obliges the state to steer overall health system activity in an ethically grounded as well as a financially efficient manner. Regulation, as a central instrument of stewardship, must from this perspective similarly satisfy these two basic requirements calling for ethical and efficient state behaviour. Failing to regulate entrepreneurialism adequately in the health sector would be a serious breach of the state’s role as a responsible steward.

A parallel dimension of this period of expanding regulatory responsibilities has been the growing recognition that ‘good regulation’, to use Chinitz’s phrase from Chapter 2, is a complex and often tedious process. As Rico and Puig-Junoy suggest in Chapter 3, it is substantially more complicated to regulate
a competitive market than it is to regulate a traditional private-sector monopoly such as the public utility model. The number of issues involved is greater than it initially appears, and finding an effective balance among them so as to accommodate the major concerns of key actors is inherently difficult. Avoiding the types of negative outcome expressed in antagonistic definitions of regulation put forward by many micro-economists – self-serving protectionism, regulatory capture, etc. (see section on ‘Conceptualizing regulation’) – further complicates the process. This complexity itself often comes as a shock to micro-economists, who have been trained to see regulation only in one narrow dimension – that is, economic – and who frequently assume that regulatory matters should be decided solely on the basis of technical efficiency.

It is partly in response to the difficulty of designing effective regulation, and to the mix of values as well as technical issues that suffuse regulatory decisions, that policy-makers have sought new strategic options during the 1990s, seeking more nuanced instruments that better fit differing national contexts. In its design and implementation, regulation no longer needs to be considered as a ‘black box’ that a policy-maker either adopts or avoids. Rather, the art of regulating well appears to be related to the type and form of regulation, and to the recognition that regulation is a means of achieving a desired objective rather than an end in itself. Moreover, as more conceptually minded economists from Arrow (1963) to Sen (1978) to Rice (1998) have noted, the market-style mechanisms that form the heart of entrepreneurial initiatives are inherently incapable, in themselves, of either comprehending or addressing the major normative goals that most governments posit for the health sector.

Similarly, the recent increase in entrepreneurial behaviour in European health systems need not necessarily be associated with any substantial increase in privatization in the health sector. As examined elsewhere (Saltman and von Otter 1992; LeGrand and Bartlett 1993; Saltman 1997), there is no inherent relationship between the introduction of competitive mechanisms into publicly operated health services and the transfer of these public providers to private ownership. Indeed, one can argue convincingly that the introduction of market-style mechanisms within publicly operated providers can – by bringing greater efficiency, effectiveness and patient responsiveness – preserve the future of publicly owned providers and of the social values they embody. The wisdom of this position has been demonstrated across several countries of western Europe (the United Kingdom, Sweden, Finland and parts of Spain and Italy) as well as of central Europe (in particular Hungary and the Czech Republic) (Saltman and Figueras 1997; Saltman et al. 1998). A parallel theme has been picked up in recent work on hospital restructuring conducted by the World Bank (Harding and Preker 2000). In practice, countries that have placed the greatest emphasis on carefully developing more market-like relationships within their publicly owned hospital sectors have experienced little privatization of publicly operated facilities over the past 10 years.

The analysis that follows explores the complex relationship between state regulation and entrepreneurial behaviour in four linked sections. The next section considers the multiple conflicting definitions of regulation utilized by different actors or academic disciplines, and examines the implications of these different definitions in the general approach that different schools of analysts
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take to this field. We then apply these different notions of regulation specifically to the health sector, and assess their appropriateness to the regulatory endeavour within it. Next, we review the evidence and experience with regulation as generated in the invited chapters in Part two, presenting a systematic typology for classifying different regulatory initiatives. Finally, we address the implications of this review for future policy decisions in the health sector in Europe.

**Conceptualizing regulation**

Regulation is one of the most contested issues in social organization. Beginning with Downs’ (1957) attack on traditional Weberian bureaucracy in the middle of the century, the process by which the nation state has sought to steer behaviour in non-state sectors of society has been subjected to increasingly close scrutiny. This debate has penetrated to the most basic level of defining what regulation is, as well as determining whether and when regulation can be beneficial, who should undertake it, and which organizational structures and mechanisms should be used. Different academic disciplines have come to view these and similar questions through decidedly different conceptual lenses, resulting in a public discussion that often sheds more heat than light.

Here, we briefly review recent debates concerning the concept of regulation in general and, in particular, the appropriate role of the state as regulator. Several alternative definitions of regulation are presented, followed by a consideration of the various characterizations that different schools of thought have placed on state regulatory activities.

**Differing definitions of regulation**

There is no single standard definition of regulation. Rather, there are multiple, different, frequently conflicting definitions. While each definition is grounded in the academic literature, each reflects different disciplinary perspectives, different political agendas and the different value sets that underlie these agendas.

As Chinitz suggests in Chapter 2, regulation looks rather different when approached from the different disciplinary perspectives of economics, management, law and politics. Efforts to control prices, volume, market structure or the behaviour of economic actors concern economists. Measures that interest management theorists include mutual adjustment, direct supervision, standardization and decentralized decision-making. Public management focuses on the process of designing, implementing and monitoring regulatory initiatives. Legal scholars concern themselves with related questions of law and status, while political scientists emphasize the need to make trade-offs among different interests and potential outcomes. Chinitz concludes that regulation in the real world is a constantly evolving mix of these different disciplinary dimensions.

Baldwin et al. (1998) classify the various definitions of regulation found in the academic literature into three basic categories, tied to how wide-ranging the level of control is. The first and narrowest category defines regulation as
setting forth mandatory rules that are enforced by a state agency. In this
definition, regulation may be economic or social in nature, but does not include
the criminal justice system or administrative or criminal sanctions unless there
is a relevant court decision. The second category, typically found in the polit-
cical economy literature, incorporates all efforts by state agencies to steer the
economy. This considerably broader view is seen to include state ownership
and contracting, as well as taxation and disclosure requirements. The third
and broadest category considers regulation to include all mechanisms of both
intentional and unintentional social control. Here, societal norms and values
join intentional policy initiatives to construct what is in effect an environ-
mental approach to regulation.

A similar scale of increasing comprehensiveness, but only for direct state
intervention, serves as the organizing principle for the continuum of approaches
to regulation set forward in Altman et al. (1999). Derived from work by Wallack
et al. (1991), this approach describes a continuum of four models. Seen through
the eyes of standard economic theory, regulation is understood as artificial
governmental restraint on otherwise natural and unconstrained market activ-
ity. The least interventionist is the elective model, in which the state imposes
regulation only to correct market failure. In the directive model, the state uses
its leverage as a purchaser or regulator to stimulate certain types or standards
of service. With the restrictive model, the state steps in to limit what is made
available on the market. In the most interventionist, prescriptive model, the
state itself defines the criteria for offering services on the market.

A quite opposite approach to regulation defines it in terms of the social
goods and normative values influenced by certain types of economic activity.
In this approach, normative values are the starting point and main concern,
with issues of economic efficiency being of distinctly secondary importance.
Presaging by some 50 years the now-emerging stewardship approach, Selznick
(1985) defined regulation as ‘the sustained and focused control exercised by a
public agency over activities that are socially valued’. Following a similar line
of logic, Colton et al. (1997) argue that there are two levels of state regulation
of economic actors. The least restrictive or general level involves ensuring that
companies satisfy state requirements regarding consumer protection, worker
health and safety, and environmental protection. The more restrictive, consid-
ervably tighter level of regulation is applied – citing the legal language of this
United States-based doctrine – to ‘industries affected with the public interest’.
These sectors (of which health is one) are subject to regulation as public util-
ities and must meet additional standards of public accountability, universal
access and quality of service. A key point regarding Colton et al. (1997) is the
implicit recognition that not just the health sector but all economic sectors
automatically and permanently exist within a political market, in which the
state defines the boundaries of permissible economic behaviour (Polanyi 1944).

Differing rationales

Much as there is no agreement among analysts on how to define regulation,
there is similarly little consensus on the rationale for introducing state regulation
Regulating entrepreneurial behaviour into any particular sector of the economy. Although some schools of commentators strongly support state activity, others view any active state role as self-serving and unacceptable. Thus, while the previous section described the absence of a standard definition of regulation, this section presents what is overt contradiction between the several rationales as to the motive of states in seeking to regulate.

Baldwin et al. (1998) provide three broadly different - and contradictory - rationales for regulation. The first is public interest. This refers to the set of normative assumptions that ‘good government’ can be had in a democratic society, and that it can serve the best interests of the vast majority of the population. In the economic sector, the public interest position holds that the state acts as an agent for the general public interest when it intervenes to tackle market imperfections. As Baldwin et al. (1998) note, consistent with this view is a belief in the trustworthiness and public spiritedness of both experts and regulatory officials. Current rationales for the state as steward draw on this viewpoint, although stewardship has efficiency as well as ethical dimensions (Saltman and Ferroussier-Davis 2000).

A second, quite different understanding of the rationale for state regulation emerged from the writings of political scientists in the 1930s and 1940s (Lasswell 1936; Long 1949). These scholars put forward what has become known as the interest group perspective, in which the implementation of regulatory measures is seen to reflect the clash of various interested parties, with the outcome of this power struggle ranging from open pluralist competition to the absorption of the most powerful groups into a corporatist state position (Baldwin et al. 1998). This perspective emphasizes process over content and views regulation as just one more form of normal political activity in a pluralistic society.

The third approach draws on micro-economic theory to discern rational self-interest in the behaviour and decisions of each separate individual involved in a regulatory undertaking. Disaggregating the state into the individuals that run it, this individual self-interest school sees the personal preference of each separate decision-maker as the central explanation for everything that happens in the regulatory arena. In this perspective, regulation is just one more commodity, 'bought by the economically powerful and used in a manner to gain further wealth' (Baldwin et al. 1998: 10). Among the different variants of this position are: the capture theorists (state regulatory agencies primarily serve the interests of the regulated company or industry); the closely related ‘special interest’ and ‘rent-seeking’ theorists (individuals and companies prefer regulation since it can be used to restrict entry of new firms and increase retained profits); and the public choice theorists (public officials are primarily concerned with easier jobs, higher salaries and building empires that enhance their individual careers). In this view, state regulation inherently distorts economic efficiency and, consequently, should be minimized or eliminated.

A more market-friendly, transaction-based view of the state’s regulatory role can be seen in Chapter 2, drawing on Williamson’s studies of hierarchy and markets (Williamson 1975, 1985). In Chinitz’s assessment, Williamson’s framing of the critical strategic decision for all organizations in terms of ‘make or buy’, leavened by concerns about opportunism (manipulation) and bounded rationality (limits to knowledge), suggests that state regulation should act as an
essentially neutral technical tool by which to ensure low transaction costs and thus greater economic efficiency. In Chinitz’s phrase, the state’s role should ‘improve the manner in which different institutional structures allow participants to see through to completion the transactions in which they are engaged’. The rationale for state regulation thus becomes that it serves as an enabler, a mechanism by which to improve the operation and efficiency of economic undertakings. Such state functions would include establishing the physical and legal infrastructure necessary to do business, a role that has become important in the transition economies of central and eastern Europe (Nunberg 1999).

One particular outcome that has emerged from the public interest rationale for state regulation can be seen in the recent history of the state in Europe (Majone 1994, 1996). From the welfare state that guaranteed and often itself provided basic services to the national population, a new ‘regulatory state’ is emerging that understands its role as enabling (but not necessarily providing) traditional human services as well as, in a new departure, enabling markets to exist and thrive in a variety of formerly state-run sectors (transportation, telecommunication, utilities, etc.). While there are commentators with both normative and substantive concerns about this transformation, particularly in the health sector (Dahlgren 1994; Diderichsen 1995), this new rationale places the regulatory function at the heart of the emerging new state structure.

Two additional explanations have been suggested for the specific manner in which the state engages in regulatory initiatives. Certain authors separate the influence of organizational or institutional interest from both interest group and self-interest, since they view institutions not purely as a group of individuals but as shaped in action, knowledge and preference by organizational rule and social environments (cf. March and Olsen 1984; Immergut 1992). ‘Regulation is thus seen as shaped not so much by notions of the public interest or competitive bargaining between private interests but by institutional arrangements and rules’ (Baldwin and Cave 1999: 27). Other commentators have argued that the content of regulation may not be primarily linked to any of the forces mentioned above, but reflect rather the force of ideas within civil society at a given historical moment (Hood 1995).

The mechanisms of regulation

Despite wide-ranging definitions and contradictory rationales, there is broad agreement about the source and general mechanisms of regulation. Regarding who regulates, initiatives can be instituted not just at national level but, depending on the structure of governmental arrangements, at regional and local municipal levels of administration as well. With the emergence of new pan-European agencies, European Union regulation can also be supranational. While most regulation in Europe is conducted by some form of government department, it can be undertaken by independent regulatory agencies (for example, OFTEL in the United Kingdom to regulate private telecommunication companies) or by self-regulatory bodies. Most countries (as well as the European Union) have provisions that give precedence to higher-level governments in case of a conflict between different regulatory regimes.
Regulating entrepreneurial behaviour

The mechanisms of regulation can be grouped into two basic categories, tools and strategies, which can in turn be combined in various mixes. The basic tools of regulation are straightforward. They are traditionally premised on the ability of government to require mandatory compliance with its decisions (which, in turn, flows from the sovereignty rights of the state). The major categories are legislation, administrative decree and judicial order, one for each of the three branches of government (legislative, executive and judicial). Each of these three can be generated in many different forms and formats, particularly administrative decrees, and with various degrees of finality (advisory regulations, guidelines, emergency measures, etc.). Most regulatory measures promulgated by the executive branch in a democratic society can be challenged in court by those who fear they will be adversely affected, and can be overruled if appropriate by judicial order. Litigation is expensive and time-consuming, however, and in a well-functioning system is undertaken only in the most egregious circumstances.

The use to which these basic tools are put is the realm of strategy. Here, governmental bodies have a wide and growing range of options. Indeed, one of the major changes in regulatory regimes during the 1990s has been the development of softer market-style incentives to encourage (rather than require) certain desired behaviour, particularly with regard to economic efficiency (Osborne and Gaebler 1992; Majone 1996). Baldwin and Cave (1999) put forward the following (occasionally overlapping) framework of potential regulatory strategies: (1) command and control; (2) self-regulation and enforced self-regulation; (3) incentive-based regimes (taxes and subsidies); (4) market-harnessing controls (competition laws, franchising, contracts and tradable permits); (5) disclosure regulation; (6) direct governmental action; (7) legal rights and liabilities; and (8) public compensation/social insurance schemes. As discussed on pp. 20–1, categorizing command and control as a form of regulation generates several difficult questions, which are considered below in the discussion of who is regulated. It also seems wise to consider the concept of incentives (as above) to have both positive and negative dimensions (Saltman, in press). The implications of these different strategic alternatives for regulating the health sector are considered on pp. 19–24.

In thinking about the logic of these various strategies, regulation clearly can have two quite different orientations: it can seek either to achieve compliance and/or disclosure, or to achieve deterrence and/or institute sanctions. Furthermore, the outcome from different regulatory strategies can be fluid as well as static in character, in that the boundaries between state and market, and the focus of specific regulatory initiatives, can shift over time. These changes can be unintentional as well as intentional in terms of how they affect the outcome achieved. Lastly, as implied earlier about the emerging ‘regulatory state’, regulation can be designed to be either pro-competitive or anti-entrepreneurial in its impact.

Beyond tools and strategies, there lies the difficult but essential process of implementation. As every regulator is aware, it is one thing to develop a good regulatory regime on paper, but it is quite another to put that regime into operation successfully. Implementation involves its own separate set of strategic assessments and political skills (Pressman and Wildavsky 1973; Walt 1998),
Balancing regulation and entrepreneurialism

which have evolved to differing degrees within health systems in Europe (Rathwell 1998). Successful implementation also requires a cadre of trained regulators and of competent managers inside regulated institutions, both capable of ferreting out (rather than succumbing to) bureaucratic inertia and institutionalized corruption. Recent experience in the countries of central and eastern Europe suggests how important and complicated each of the additional aspects of implementation can be (see Chapter 5) (Nunberg 1999).

Regulating the health sector

Bringing the general approach of regulation to bear on the specific characteristics of health care systems is an inherently complex process. As explored in the previous sections, regulation is a wide-ranging set of activities comprising a considerable array of specific tools and strategies. Similarly, the health sector is a sprawling mix of programmes and services ranging from acute to preventive, from individual to population, and from inpatient to primary care, dental, mental and occupational health services. Melding these two unwieldy entities into a clear and internally consistent package is not easy. Not surprisingly, in the health sector as in other human service sectors (education, for example), policy-makers typically settle for reasonable approximations and imperfect solutions, knowing that even these will be hard to implement and sustain over time. This section considers how the general models, strategies and tools just described can be applied within the specific conditions of the health sector.

Two dimensions of health sector regulation

In thinking about the application of the available range of regulatory tools and strategies to the health sector, it is useful to separate out two different public purposes for taking regulatory action: these can be termed ‘policy objectives’ and ‘managerial mechanisms’. Each has its own specific function and rationale, but each needs to be connected closely to the other to achieve its goals. This section considers how the general concept of regulation applies to these two different dimensions of policy-making in the health sector.

The first dimension of regulatory activity can be termed social and economic policy objectives. It is normative and value-driven in nature, concerned with specific policy goals – with ends and objectives – and with the broad public interest (which may be seen differently in different countries). Core policy goals are typically expressed in the national constitution (or societal consensus to the same end), in key legislative acts and in the overall organization of socially sentinel sectors such as health care. These societal decisions are reflected, for example, in the choice to create a national health service or a system based on statutory health insurance. Such value-driven decisions tend to change only infrequently, typically as a consequence of major historical events such as wars (the foundation of the British National Health Service (NHS) in 1948), the end of dictatorships (the change from social insurance to NHS-type systems in Portugal and Spain) or as a result of political revolutions (as in central
14 Regulating entrepreneurial behaviour

Table 1.1 Social and economic policy objectives

- Equity and justice: to provide equitable and needs-based access to health care for the whole population, including poor, rural, elderly, disabled and other vulnerable groups
- Social cohesion: to provide health care through a national health care service or to install a social health insurance system
- Economic efficiency: to contain aggregate health expenditures within financially sustainable boundaries
- Health and safety: to protect workers, to ensure water safety and to monitor food hygiene
- Informed and educated citizens: to educate citizens about clinical services, pharmaceuticals and healthy behaviour
- Individual choice: to ensure choice of provider, and in some cases insurer, as much as possible within the limits of the other objectives

European countries after 1990). Within this core dimension of health sector policy-making, however, certain policy expectations can also evolve and mature in normal political times. In Europe in the 1990s, for instance, a variety of health sector reforms sought to address more explicitly broad policy objectives regarding the overall health of the population (WHO 1999a).

The broad societal focus of this first dimension of regulatory activity in the health sector emphasizes a series of common concerns that influence both western European and the countries of central and eastern Europe (CEE) and the former Soviet Republics that are now loosely linked in the Commonwealth of Independent States (CIS) alike. Examples of the more common concerns are presented in Table 1.1. The central distinguishing characteristic of these objectives is that they are population-wide and that they typically lead to mandatory national requirements on all actors, including the private not-for-profit and for-profit sectors. To achieve their stated objectives, these broad policies also need to influence government decisions in other sectors such as education, transport, employment, housing and agriculture (WHO 1999a).

The second dimension of regulatory activity can be termed the health sector management mechanisms. This level is practical and operational and is concerned with the specific regulatory mechanisms through which decision-makers seek to attain the type of policy objectives set out in Table 1.1. These means are largely technical in nature, emphasizing efficient and effective management of both human and material resources. They may or may not have a direct impact on the ability of the overall health system to achieve its broad policy objectives. These managerially oriented mechanisms may have a mixed public/private character, reflecting the complex profusion of different provider arrangements across the health sector. Their managerial focus means that they tend to emphasize micro-level activities at sub-sector or even at facility/institution level.

The tightly defined institutional character of this second, management dimension of regulation can be seen in the types of activity that fall within its purview. These comprise a familiar litany to Ministry of Health and parliamentary social committee decision-makers, including the topics listed in Table 1.2. As that list suggests, these are predominantly mechanisms that affect health care
Balancing regulation and entrepreneurialism

Table 1.2  Health sector management mechanisms

- Regulating quality and effectiveness: assessing cost-effectiveness of clinical interventions; training health professionals; accrediting providers
- Regulating patient access: gate-keeping; co-payments; general practitioner lists; rules for subscriber choice among third-party payers; tax policy; tax subsidies
- Regulating provider behaviour: transforming hospitals into public firms; regulating capital borrowing by hospitals; rationalizing hospital and primary care/home care interactions
- Regulating payers: setting rules for contracting; constructing planned markets for hospital services; developing prices for public-sector health care services; introducing case-based provider payment systems (e.g. diagnostic-related groups); regulating reserve requirements and capital investment patterns of private insurance companies; retrospective risk-based adjustment of sickness fund revenues
- Regulating pharmaceuticals: generic substitution; reference prices; profit controls; basket-based pricing; positive and negative lists
- Regulating physicians: setting salary and reimbursement levels; licensing requirements; setting malpractice insurance coverage

management capabilities, and typically include measures associated with greater operating efficiency and effectiveness. Some of these regulatory instruments - such as the development of planned markets for hospital services and the concomitant transformation of public hospitals into public firms; or the rationalization of relations between hospitals and primary care providers - lie at the core of recent health reforms across western as well as central Europe (Saltman and Figueras 1997; Saltman et al. 1998). These and several other recent regulatory mechanisms adapted from private-sector instruments have been part of a concerted effort to implement the 'new public management' movement within the health sector (Hunter 1997).

The specific choice of mechanisms as well as the balance among them differs between countries, depending on the precise configuration of broad policy objectives as expressed in the overall design of the health sector. For example, anti-trust concerns are substantially greater in the more competitively structured post-1997 health system in the Netherlands than in the predominantly corporatist arrangements found in Germany. How policy-makers define regulation, and which rationale they adopt to justify or reject specific regulatory mechanisms, also plays an important role in the overall regulatory design adopted. The key point here, however, is that, while policy objectives and management mechanisms differ from each other conceptually, they must be designed to fit together if a government is to have a coherent and sustainable regulatory framework in its health sector.

This two-part framework - policy objectives and managerial mechanisms - describes the role of regulation within the health sector in a manner consistent with the general role of regulation set out earlier. The emerging 'regulatory state', for instance, has clear responsibilities within both the social policy and institutional management dimensions found in the health sector. Several of the general definitions of regulation are visible within the health sector as well. Selznick's (1985) stress on controlling 'socially valued activities' and the
Regulating entrepreneurial behaviour

emphasis of Colton et al. (1997) on ‘industries affected with the public interest’ are captured by the concept of social and economic policy objectives. Similarly, the dominant focus of regulation in the health sector incorporates the first two of three definitions of Baldwin et al. (1998) (e.g. the narrow rule-setting and enforcement approach, together with the wider notion encompassing all state efforts to steer the economy). One could also choose to apply to the health sector any of the three main characterizations presented as the rationale for introducing regulation (public interest, self-interested groups and rational self-interest). In all these regards, the conceptualization of regulation developed earlier fits with the approach presented here for application to the health sector.

Lastly, while health care is the major societal sector charged with pursuing the objective of improving the health of the population, the overall design of other sectors such as education, transport or agriculture should also reflect this objective. Regulation to ensure health gain necessarily addresses actors outside as well as inside health care. The types of intersectoral regulatory concerns involved are presented in Table 1.3.

Allocating regulatory roles in the health sector

Within the health sector, a wide range of different public sector bodies can be involved in regulation. The three major pillars of a democratic state – the legislature (parliament), the executive (government and government administration) and the judiciary (the courts) – each play a clearly delineated role. Other governmental, quasi-governmental and non-governmental actors may also be expected or designated to act as regulators. Some countries rely on devolved public responsibility to either regional (county, Land, autonomous community) or local (municipal) authorities, while others delegate ‘self-regulatory’ authority to various private-sector entities (licensure to medical associations, insurance to sickness fund associations). Some countries utilize independently managed national agencies (National Board of Health, Office of Prices and Tariffs, National Insurance Fund, etc.). Who will be responsible for what is contingent upon a range of factors, including the type of activity being regulated, the segment of the health system being regulated (hospitals, physicians, etc.), the capacity of various actors within that segment and a variety of national factors including institutional structure and cultural traditions.

Regulatory activity itself, in the health sector as elsewhere, consists of legislation, implementation, monitoring and evaluation, enforcement and judicial supervision. Although legislation often focuses on social and policy objectives, setting out the broad health system institutional framework, once a health system is well established, legislation can also mandate mechanisms of health sector management. Once legislation is enacted, the variously designated public, mixed public–private or private agencies issue administrative regulations that seek to implement the relevant regulatory provisions. This is formally termed ‘promulgation’ and is particularly time-consuming in the health sector, with its confluence of strong yet divergent interests along with the need to accommodate the inherent complexities of the medical decision-making process.
Table 1.3 Intersectoral dimensions of health-related regulation

<table>
<thead>
<tr>
<th>Broad policy objectives</th>
<th>Tax system</th>
<th>Employers in general</th>
<th>Health care (details in tables on sub-sectors)</th>
<th>Education</th>
<th>Transport</th>
<th>Agriculture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equity and justice</strong></td>
<td>Minimization of tax evasion</td>
<td>Mandatory equal job opportunities for the physically disabled, minorities, etc.</td>
<td>Access and treatment only according to need</td>
<td>Access and educational offers according to ability</td>
<td>Provision of public transport</td>
<td>—</td>
</tr>
<tr>
<td><strong>Social cohesion</strong></td>
<td>Progressivity of income taxes</td>
<td>Taxes for enterprises (in addition to income tax)</td>
<td>Contribution relating to income/wealth, not health status</td>
<td>Paying for education from taxes</td>
<td>Public subsidies for public transport</td>
<td>—</td>
</tr>
<tr>
<td><strong>Informed and educated citizens</strong></td>
<td>Tax exemptions for educational material or institutions</td>
<td>—</td>
<td>Patient information and health education</td>
<td>Effectiveness/quality of educational system</td>
<td>—</td>
<td>Customer information labelling</td>
</tr>
<tr>
<td><strong>Health and safety</strong></td>
<td>Higher taxes on products/services damaging health</td>
<td>Workers’ health and safety; working hours; occupational health service; protective equipment (e.g. helmets)</td>
<td>Protection of health care personnel; effectiveness/quality of health care</td>
<td>Safety on way to school; mandatory vaccination programmes; school nurses</td>
<td>Industry: mandatory installation of seat-belts and airbags; Drivers: mandatory use of seat-belts; speed limits</td>
<td>Hygiene requirements for food production, inspection and quality control</td>
</tr>
<tr>
<td>Broad policy objectives</td>
<td>Intersectoral regulatory responses</td>
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<tr>
<td>Tax system</td>
<td>Employers in general</td>
<td>Health care (details in tables on sub-sectors)</td>
<td>Education</td>
<td>Transport</td>
<td>Agriculture</td>
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<tr>
<td>Sustiability/</td>
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<tr>
<td>protection of the</td>
<td>Matching taxes and public</td>
<td>Sustainability of financing and capital*</td>
<td>Sustainability of financing and capital*</td>
<td>Industry: limits for exhaust pollution</td>
<td>Restrictions on pesticide use</td>
<td></td>
</tr>
<tr>
<td>interests of future</td>
<td>expenditure</td>
<td></td>
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<tr>
<td>generations</td>
<td>Environmental protection</td>
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<td></td>
<td>requirements</td>
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<tr>
<td>Individual choice</td>
<td></td>
<td>Choice of provider, payer, etc.</td>
<td>Choice of school or university</td>
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<tr>
<td>Rising standard of</td>
<td>Post-tax profits</td>
<td>Anti-trust/pro-competition laws</td>
<td>Ensuring investment; increasing efficiency</td>
<td></td>
<td></td>
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<tr>
<td>living/ economic</td>
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<tr>
<td>growth</td>
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</table>

* in column 3 of Tables 1.6-1.10. in column 3 of Tables 1.6-1.10. P in column 3 of Tables 1.6-1.10. P (first item) and Q (second item) in column 3 of Tables 1.6-1.10. S in column 3 of Tables 1.6-1.10. Columns 1 and 2 of Tables 1.6-1.10.
Different health sector actors bring different strengths and weaknesses to the structuring, implementation, evaluation and enforcement of regulatory measures. In a useful summary of the characteristics of different regulatory actors generally, Baldwin and Cave (1999: 72) suggested the following:

- Self-regulators tend to be strong on specialist knowledge but weak on accountability to the public;
- Local authorities strong on local democratic accountability, weak on coordination;
- Parliament strong on democratic authority, weak on planning;
- Central departments strong on coordination with the government, weak on neutrality;
- Agencies strong on expertise and combining functions, weak on neutrality;
- Directors general strong on specialization and identification of responsibility, weak on spreading discretionary powers.

A further issue concerns the appropriateness of allowing the same actor simultaneously to set the rules as well as to supervise their implementation. Once again, institutional structures and national traditions often have an influential role in the allocation of regulatory authority among different competing groups.

**Strategies for health sector regulation**

When the general framework of strategies and tools developed above is applied to the health sector, it quickly becomes apparent that European policy-makers have many strategic options with which to structure health-related regulation. The scope of these options has expanded during the 1990s, reflecting the inclusion of approaches adapted from other sectors of the economy - for example, the notion of independent regulatory agencies for public utilities. These potential strategies now span considerable territory and, while they are formally designed to achieve the same basic social and economic objectives, they have notably different internal logics, secondary consequences and - once implemented - mechanisms.

The range of choice that these various strategies represent is already visible in how state authority is currently exercised in the health sector. Present-day options can be arranged in a continuum from the strongest to the weakest degree of regulatory involvement. As Table 1.4 indicates, however, the strongest form of state intervention is not in fact regulation at all, but rather a military-style command-and-control model of authority. In practice, health sector entities that are wholly owned and operated by the state (or devolved to regional or local government on the same operating basis) are subject to a top-down form of administrative control that is qualitatively different from that found elsewhere in the health sector. Command-and-control in the health sector, as in the military, demands obedience rather than negotiation and/or litigation. This understanding of command-and-control is the one adopted by Baldwin et al. (1998), who note that, as one example, the United Kingdom’s Competition Commission (the former Monopolies and Mergers Commission) did not concern itself with anti-competitive practices by utilities until they were privatized. It is also consistent with the approach to regulation set forward in the concept of the ‘regulatory state’ (Majone 1994, 1996).
Table 1.4 Continuum of state authority in the health sector

<table>
<thead>
<tr>
<th>Degree of state authority and supervision</th>
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<tbody>
<tr>
<td><strong>Stronger</strong></td>
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<tr>
<td>Command-and-control</td>
</tr>
<tr>
<td>• Entities with full state ownership as part of the health sector hierarchy</td>
</tr>
<tr>
<td>• hospitals directly managed by the health service/health authorities</td>
</tr>
<tr>
<td>• tax-based payers (pre-1991 district health authorities in the United Kingdom, counties in Sweden)</td>
</tr>
<tr>
<td>• Entities with full state ownership but managerially independent</td>
</tr>
<tr>
<td>• autonomous hospitals in tax-funded countries (NHS trusts in the United Kingdom)</td>
</tr>
<tr>
<td>• public hospitals in countries with social health insurance (Austria, Germany)</td>
</tr>
<tr>
<td>• hospitals as ‘public firms’ (tax-funded countries)</td>
</tr>
<tr>
<td>• Private not-for-profit entities with statutory responsibilities</td>
</tr>
<tr>
<td>• sickness funds</td>
</tr>
<tr>
<td>• associations of physicians affiliated to social health insurance</td>
</tr>
<tr>
<td>• Private not-for-profit entities without statutory responsibilities</td>
</tr>
<tr>
<td>• private not-for-profit hospitals (Belgium, Germany, Netherlands)</td>
</tr>
<tr>
<td>• private not-for-profit social and home care providers</td>
</tr>
<tr>
<td>• Private for-profit providers with continuous service relationships with tax-funded and/or statutory social health insurance payers</td>
</tr>
<tr>
<td>• general practitioner fundholders (United Kingdom)</td>
</tr>
<tr>
<td>• office-based general practitioners</td>
</tr>
<tr>
<td>• office-based specialists (Germany)</td>
</tr>
<tr>
<td>• for-profit hospitals listed in regional hospital plans (Germany)</td>
</tr>
<tr>
<td>• for-profit hospitals contracted by public payers (Italy, Portugal)</td>
</tr>
<tr>
<td>• Private for-profit companies</td>
</tr>
<tr>
<td>• non-contract for-profit hospitals</td>
</tr>
<tr>
<td>• pharmaceutical companies</td>
</tr>
<tr>
<td>• medical supply companies</td>
</tr>
<tr>
<td>• for-profit private insurance companies</td>
</tr>
<tr>
<td><strong>Weaker</strong></td>
</tr>
<tr>
<td>Steer-and-channel regulation</td>
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</tbody>
</table>

In Table 1.4, the critical break occurs between ‘entities with full state ownership as part of the health sector hierarchy’ and ‘entities with full state ownership but managerially independent’. As this break suggests, once one introduces planned market mechanisms into a publicly owned and operated health sector, one no longer has a command-and-control structure of authority (Saltman and von Otter 1992). Instead, when for instance publicly owned hospitals are transformed into public firms, hospital-level managers acquire substantial decision-making autonomy on such issues as service provision, staffing mix and levels, and some aspects of salary levels. As Table 1.4 indicates, once such
managerial autonomy exists, then those publicly owned institutions become subject to what can be termed ‘steer-and-channel’ regulation. This distinction reflects the basic consideration that independent decision-making capacity at institutional level in turn generates a need for state regulation to ensure that those decisions remain consistent with broader social and economic policy objectives.

An additional point about Table 1.4 concerns the regulation of for-profit companies or providers, where state authority is weakest. Consistent with the argument made by Colton et al. (1997), weak state authority still involves a relatively wide range of regulatory measures (at least in western Europe). Beyond the basic industrial measures applicable to all sectors of the economy (worker health and safety, etc.), even the least regulated elements of the health sector must comply with a variety of social and economic policy objectives. Hence, ‘less regulated’ in the health sector may still be considerably more regulated than in sectors of the economy that are not ‘affected with the public interest.’

This existing distribution of state authority, and in particular the important distinction between military-style command-and-control as against a regulatory steer-and-channel approach, defines the context within which various potential regulatory strategies can be applied. As Table 1.5 suggests, after excluding command-and-control, there are five general types of steer-and-channel options: decentralization (four variants), enforced self-regulation, accreditation, independent regulatory agencies and intersectoral cooperation. As with all public policies, each general type has its distinct advantages and disadvantages. Moreover, these different strategies can be used in combination as well as singly, for example by requiring accreditation of hospitals that, as public firms, are also subject to other extensive steer-and-channel mechanisms.

The four different variants of decentralization are also typically conjoined with other regulatory strategies, in that they reflect changes in organizational structure as well as in the distribution of decision-making authority. Deconcentration, devolution, delegation and (quite differently) privatization are commonly considered strategic options for health system reform (Hunter et al. 1998). Deconcentration refers to passing the power to set regulatory acts from the national government to independent government agencies. Devolution applies to passing regulatory power to regional or local authorities (who may choose to further deconcentrate or delegate those powers). In the case of delegation, power is typically granted to non-governmental actors, often with legal backing. The delegation of regulatory authority to either funders (insurers) or providers is typically described as ‘self-regulation’ or (when supplemented by state supervision) ‘enforced self-regulation’. While tax-funded health care systems tend to rely on deconcentration and devolution, delegation is more commonly found in systems funded by social health insurance. Privatization involves a fundamental shift from predominantly public-sector to predominantly private-sector authority. Although rarely used, it has been adopted for primary care provision in the transition countries of central and eastern Europe (see Chapter 10) (Saltman and Figueras 1997).

Self-regulation refers to a state-generated mandate that allows certain professionals or enterprises to set standards for the behaviour of its membership
Regulating entrepreneurial behaviour

Table 1.5 Strategies for health sector regulation

<table>
<thead>
<tr>
<th>Social and economic policy dimension</th>
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<tbody>
<tr>
<td>Strategies</td>
</tr>
<tr>
<td>(Military command-and-control)</td>
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<tr>
<td>Steer-and-channel</td>
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<tr>
<td>Decentralization</td>
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<tr>
<td>- Decentralization - delegation</td>
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<tr>
<td>- Designation</td>
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<td>- Evaluation</td>
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<tr>
<td>- Enforced self-regulation</td>
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<tr>
<td>- Accreditation</td>
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<tr>
<td>- Independent regulatory agencies</td>
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<td>- Intersectoral cooperation</td>
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<tr>
<th>Institutional management dimension</th>
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<tbody>
<tr>
<td>Strategies</td>
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<tr>
<td>(Military command-and-control)</td>
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<td>- Enforced self-regulation</td>
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<td>- Accreditation</td>
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<tr>
<td>- Independent regulatory agencies</td>
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<td>- Intersectoral cooperation</td>
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(Baldwin and Cave 1999). These arrangements vary considerably in Europe in the extent of governmental delegation (see, for example, Graham 1994). Self-regulation can be viewed as a continuum from the purely private (with no governmental delegation) to various forms of publicly mandated delegation. Private self-regulation can be found within some professional organizations or within voluntary organizations, but the lack of state-enforced compliance renders this form of self-regulation too weak to sustain most policy objectives. Typical examples of publicly mandated regulation in health care are professional self-regulation by physicians, dentists and pharmacists, and in some countries also nurses, by health insurance funds in countries with social health insurance and, at least to a certain degree, by the pharmaceutical industry (e.g. in the United Kingdom).

The major advantages of self-regulatory delegation have been summarized as follows: high commitment to own rules; well-informed rule-making; low cost of government; close fit of regulatory standards with those seen as reasonable by actors; greater comprehensiveness of rules; potential for rapid adjustment; more effective enforcement and complaints procedures; and potential to combine with external supervision (Baldwin and Cave 1999). Conversely, self-regulation also has potential weaknesses: self-serving rules; meddling in management decisions; complex rules; high cost of approving rules; closed rule-making procedures; weak enforcement; lack of public trust; problematic legal supervision; and potential desire of the public for governmental responsibility (Baldwin and Cave 1999).

Ayres and Braithwaite (1992) have further differentiated between ‘enforced self-regulation’ and ‘co-regulation’. In enforced self-regulation, the promulgation of the rules is delegated to non-governmental actors, while the enforcement can be done either (1) publicly or (2) privately but publicly mandated.
and monitored. In the case of ‘co-regulation’, typically the government ratifies privately written regulation. Although health care systems across Europe have some examples of private self-regulation without state enforcement, publicly mandated self-regulation is more common – normally coupled with the threat of public enforcement.

Accreditation and licensing are specifically quality-oriented strategies. They are both constructed on two main components: external review and fixed standards. However, as Scrivens discusses in Chapter 4, these two approaches differ in that accreditation traditionally focuses on a higher standard and has been voluntary and self-funding (e.g. the institution seeking accreditation pays the costs), while licensure typically focuses on minimum standards and has been mandatory and state-funded. The establishment of mandatory accreditation within several European health systems, including those of Belgium and France, has blurred these distinctions, transforming accreditation into a formal dimension of state regulation. This has become particularly important as publicly operated health systems in these countries have allowed more entrepreneurial activity, particularly in the hospital sector, which in turn has raised concerns about consistent quality of care. As a strategic option, however, accreditation and licensure have typically been used as only one component of a multi-pronged set of regulatory initiatives.

The deconcentration of governmental regulatory power to independent regulatory agencies is not widely utilized in health service sectors in Europe. These independent agencies are unique in the public sector in that they combine specialized expertise and fact-finding with a judicial decision-making function (Baldwin et al. 1998). Most state health-related regulatory activity at the national level, including food and drug safety, are handled by departments within the Ministry of Health or, in the Nordic countries, by semi-autonomous national boards still subject to ministry management. There are some exceptions, however, such as the establishment of the European Medicines Evaluation Agency (EMEA) or the Agence Nationale d’Accréditation et d’Évaluation en Santé (ANAES) in France, which is charged with the accreditation of hospitals.

Policy-makers can also adopt extrasectoral (what WHO calls intersectoral) strategies in pursuit of policy objectives. One common strategy has been to rely on taxation mechanisms to promote better health. A prime example is special taxes on tobacco to deter people from smoking (Pekurinen and Valtonen 1987; WHO 1999b).

Assessing recent experience with regulating entrepreneurial behaviour

Recent regulatory initiatives in European health systems have sought to balance reform-driven efforts to stimulate greater entrepreneurialism with legislatively mandated requirements to maintain existing social and economic policy objectives. Policy-makers have had to accommodate the differing rationales and expectations that various health sector actors bring to the regulatory process, seeking strategies and tools with which to establish effective yet not
overly restrictive frameworks to steer institutional decision-making. Previous sections have explored different types of regulatory measure and different purposes to which they might be applied. This section builds on those conceptual distinctions to examine recent practical experience in Europe in devising a workable balance between regulation and entrepreneurialism.

We pursue this objective through two related but different analytical approaches to the available evidence. First, we lay out a systematic four-part framework through which to conceptualize recent regulatory measures in terms of their relative impact on entrepreneurial and innovative behaviour across the entire health care system. This is followed by an assessment of the current status of entrepreneurial activity in six key sub-sectors of the health system (hospitals, general practice, social care, dental care, pharmaceuticals and insurance) and the likely impact of recent regulatory measures in enhancing or retarding the range and scope of that activity. Examples utilized in both analytical approaches draw considerably on the chapters in Part two.

Assessing recent experience through a systematic framework

In thinking about the relationship between regulation and entrepreneurialism, one can place recent experience within four distinct categories. The first, regulation that stimulates entrepreneurial opportunities, needs to be differentiated from a second, regulation that promotes competition but restricts the entrepreneurial freedom of individual actors. This differentiation is, however, not as clear-cut as it may initially appear. A considerable degree of regulation restricts individual entrepreneurs in the short term in order to facilitate sustainable competitive markets in the long term. Pro-competitive regulation can thus either stimulate or restrict short-term entrepreneurial behaviour. A third category of regulation restricts entrepreneurial decisions as a way to safeguard the social and economic policy objectives discussed above. A fourth category concerns regulation restricting entrepreneurial freedom that cannot be directly associated with specific social and economic policy objectives.

These four categories provide a conceptual template with which to organize existing and potential regulatory measures that affect entrepreneurial activity in the health sector. Many of these measures, shown in detail in Tables 1.6–1.10, are drawn from the chapters in Part two. Others reflect broader social and economic policy objectives in society at large, and are indicated in the tables under the heading ‘GE’, for general economy. Lastly, a few measures (particularly in the first category) represent conceptual possibilities that would in theory encourage entrepreneurialism, but which no European government has chosen to implement.

As noted above, a health sector actor needs to have some managerial autonomy to be an appropriate candidate for state regulation. Health care entities that are an indivisible part of the state hierarchy (cf. Table 1.4), such as those without any decision-making independence, are part of a command-and-control structure of authority and thus cannot be considered to be regulated.
Balancing regulation and entrepreneurialism

Consequently, for health care organizations that are fully incorporated into state administration, the most basic initiative to stimulate entrepreneurial opportunity would be to grant these health care actors some managerial independence – in effect, to restructure these organizations into suitable subjects for state regulation. While recent evidence suggests that many publicly operated health care systems have sought to introduce this type of partial managerial independence among providers on the supply side of their health care systems (Saltman and Figueras 1997; Saltman et al. 1998), policy-makers in some countries where health care is funded by social insurance have sought to convey limited autonomy to publicly accountable funders on the demand side as well.

Turning to the four different categories of regulation, the first, regulation that stimulates entrepreneurial opportunities in the health sector, concerns efforts to develop a more competitive environment among health sector institutions and professionals. Regulation specific to the health sector that fits within this first analytical category (see Tables 1.6–1.10) typically mandates certain types of funding and reimbursement arrangement. These include replacing fixed budgets with volume- or performance-based reimbursements, granting provider institutions the possibility to retain surpluses, and tax subsidies or exemptions for certain services. More radically, regulation could allow institutions to set their own fees, allow patients to choose their hospital, ambulatory care provider or third-party payer, and let subscribers elect certain peripheral benefits.

The second analytical category, regulation to facilitate sustainable competitive markets (which includes measures that may restrict short-term entrepreneurial behaviour), incorporates an array of anti-trust/competition laws taken on board from the general economy. Regulation specific to the health sector mainly addresses issues of organizational structure and pro-competitive behaviour. Organizational structure issues include: setting minimum standards, such as through requirements for licensing, accreditation or certification (see Chapter 4); ownership of health care institutions; and preventing monopolies through restrictions on horizontal and vertical mergers. Regulation addressing pro-competitive behaviour includes measures to reduce adverse selection by health care payers and providers, such as mandatory redistribution of contributions between payers as well as requirements that health insurance funds accept all applicants.

In the third analytical category, regulation to achieve normative/social objectives (such as access, social cohesion, public health and sustainable financing), regulation applicable to the broader general economy reflects restrictions on entrepreneurial behaviour adopted to protect employees, consumers and the environment (Colton et al. 1997). Regulation specific to the health sector addresses issues of capacities, entitlements, funding and reimbursement arrangements. To ensure access to health services, regulatory measures set minimum service hours for hospitals and ambulatory care providers, mandate the delivery of services to all citizens, and call for the planning of needs-based and equitably distributed capacities. The social cohesion objective is addressed by a variety of measures, such as a mandate to deliver services to all citizens, a waiting time guarantee, health care funding through community-rated or
Regulating entrepreneurial behaviour

income-related contributions (instead of risk-related premiums) and the setting of a uniform catalogue of benefits. Public health and safety concerns drive regulation in the pharmaceutical sub-sector in particular, mandating customer information and limiting advertisements for drugs. Ensuring the quality of health services leads to regulations in the hospital as well as ambulatory care sub-sectors, such as mandating health technology assessments for services to be included in the benefits catalogue; requiring regular or continuous quality assurance for health care providers; and allowing treatment only according to protocols and guidelines to ensure the appropriate use of technologies. Finally, the objective of sustainable financing leads to regulations affecting all sub-sectors. Typical measures are the setting of uniform or maximum prices (or maximum profit margins in the case of the pharmaceutical industry), regulations stipulating minimum and maximum reserve levels for health insurers, and acceptable types of investment for surplus revenues.

An additional dimension of regulation restricting entrepreneurial behaviour to ensure that social objectives are achieved is that it can incorporate (in countries where adopted) elements of professional as well as joint self-regulation that supplement or substitute for governmental regulation. This is particularly true for the objectives of access, quality and sustainable funding, while it is typically not the case for the ‘public health and safety’ objective.

Regulation weakly tied to social objectives that may be unnecessary includes restrictions on providing certain services by certain providers (such as not allowing hospitals to offer ambulatory services) and limitations on maximum practice hours. These regulations arguably are not directly linked to social and economic policy objectives in the health sector and thus can be considered potential candidates for elimination.

Assessing recent experience across different sub-sectors

The chapters in Part two review the relationship across Europe between regulation and entrepreneurialism in six separate health system sub-sectors: hospitals, general practice, social care, dental care, pharmaceuticals and insurance. Over the course of the 1990s, developments in each of these sub-sectors reflected its particular clinical, organizational and professional characteristics, as well as its centrality to national social and economic policy objectives. Moreover, consistent with the region’s diversity, there are important differences across countries and types of health system within each sub-sector – a point reinforced in its own way in each of the chapters.

Beyond this diversity, however, it is possible to discern clearly evolving patterns among the various sub-sectors in terms of the regulatory/entrepreneurial balance within them. One pattern concerns the relative strength of entrepreneurial incentives within each sub-sector. A second concerns the extent to which the present balance has been shifting in particular sub-sectors over the past decade (if it has been shifting). A third pattern concerns the extent to which such shifts have been associated with measurable changes in either the efficiency or effectiveness with which services have been delivered in that
sub-sector. Drawing on evidence collected in the chapters in Part two, this section addresses the present status of each pattern in turn.

First, with regard to the relative strength of entrepreneurialism, the scope and range of such activities are considerably more widespread in peripheral than in core clinical areas of health systems. The greatest entrepreneurial opportunities can be found in dental care (where the predominant reimbursement mechanism continues to be fee-for-service, as Holst et al. remind us in Chapter 11) and in pharmaceuticals (where development and production of new drugs is the province of global private for-profit corporations). In addition, in a recent development, Forder (Chapter 8) describes increasing experimentation with entrepreneurial mechanisms in the provision of social and home care services. Conversely, one finds that entrepreneurial initiatives have made the smallest inroads in the two most important and most expensive delivery (supply-side) sub-sectors of health systems (e.g. hospitals and primary care), as well as in what is, in policy-making terms, perhaps the most controversial and sensitive sub-sector - the funding structure (demand side).

Having drawn these conclusions, we must immediately qualify them with three caveats. The above assessments do appear to hold for most of western Europe, in tax-funded (TF) as well as in social health insurance (SHI) funded countries. Groenewegen et al. (Chapter 10), for example, make the point that even though Dutch general practitioners are technically private entrepreneurs, they have in recent years moved ‘in the direction of more professional control (e.g. recertiﬁcation) rather than more entrepreneurship’. Concerning hospitals, Busse et al. show in Chapter 6 that, even in SHI health systems, independent private not-for-proﬁt and (fewer) for-proﬁt hospitals are tightly reined in by various types of budget and reimbursement restrictions on operating funds, as well as by a variety of capital controls.

In central and eastern Europe, however, although the main premise of these conclusions is valid, it carries somewhat different characteristics. Certainly dental care and pharmaceuticals are strongly entrepreneurial. Dental care (‘stomatology’) was often the ﬁrst service delivery component of former Soviet health systems to change once the economic transition began, shifting rapidly to a fee-for-service basis. Pharmaceuticals are similarly highly entrepreneurial – perhaps too much so, when one considers that, in countries such as Hungary, pharmaceuticals absorbed 25.7 per cent of all of ofﬁcial health care expenditures in 1997 (Gaál et al. 1999). Conversely, most hospitals remain publicly owned and operated, although often devolved to local, regional or municipal governments (Gaál et al. 1999). Yet social and home care is only in its formative phase (not having been a part of the prior Semashko approach) and, in several central and eastern European countries, some outpatient policlinics have been transformed into predominantly fee-for-service operations (Gaál et al. 1999; Busse et al. 2000).

An additional caveat is that applying this broad pattern of the regulatory/entrepreneurial balance to CEE/CIS countries takes account only of ofﬁcial revenues in the health care system. As Ensor and Duran point out in Chapter 5, informal payments can comprise a considerable proportion of real health system revenue in countries like Bulgaria and Georgia. Even in central Europe,
Regulating entrepreneurial behaviour

where informal payments are estimated to comprise a lower proportion of total health sector revenues, a substantial degree of black- and grey-market entrepreneurialism still exists, particularly in the hospital sector. Hence, the conclusion that entrepreneurialism is not strong in hospitals must be adjusted for CEE/CIS countries to refer exclusively to official or above-the-table revenues.

A final caveat concerning the relative strength of entrepreneurialism is that sub-sectors with greater amounts of entrepreneurialism do not necessarily have less regulatory activity. Indeed, as Tables 1.6–1.10 suggest, in western Europe increased entrepreneurialism is typically accompanied by rapid growth in state regulatory efforts (Saltman and Figueras 1997). The third column in Tables 1.6–1.10 suggests why that is the case: policy-makers seek to channel entrepreneurial innovations in directions that are consistent with, and supportive of, the broader social and economic objectives that guide national policy for the health sector overall. The further fact that, until recently, the growth of entrepreneurialism in many CEE/CIS countries has not been accompanied by a similar growth in regulatory activity reflects far more the conceptual, organisational and administrative dilemmas of the ongoing economic transition than any new and convincing approach to the structuring of efficient and effective health care systems (see Chapter 5) (Nunberg 1999).

The second visible pattern with regard to the regulatory/entrepreneurial balance concerns how that balance has shifted during the 1990s. Drawing on the experience cited in the chapters, the central observation is that the most important shift has been in the three largest and most central service delivery areas in health systems. Interestingly, these are also precisely those areas where, in general, entrepreneurialism has been the weakest in the past. The most notable area of increase has been among hospitals. As Busse et al. document in Chapter 6, the broad general approach to hospital governance in tax-funded health systems in northern and southern Europe has shifted from command-and-control to steer-and-channel. Similar (if structurally somewhat different) efforts to loosen the decision-making reins on hospitals are noted in the SHI-funded countries of continental Europe. The central notion that underlies this reform process to grant individual hospitals a substantial measure of decision-making autonomy, either as ‘public firms’ (Saltman and von Otter 1992) or, in SHI systems, as not-for-profit private enterprises (see Chapter 6), has now been amplified and refined by the World Bank (Harding and Preker 2000) for use in (among others) CEE countries, where little of this shift has yet occurred.

A second area where there has been increased entrepreneurialism over the past decade has been among primary care providers in tax-funded systems. In Nordic and, to a limited extent, in some Mediterranean tax-funded systems (Spain and Portugal), primary care physicians have acquired greater administrative autonomy even as they continue to be publicly paid civil servants. In Sweden, some primary health centres are now being independently run for the county councils by physician groups; one district in Stockholm County (Söder) has announced a tendering process that by 2001 will place all 16 of its primary health care centres under various forms of independent management (G. Berleen, personal communication). In the United Kingdom, many general
Table 1.6 Regulating the entrepreneurial behaviour of sickness funds and other statutory third-party payers

<table>
<thead>
<tr>
<th>Pro-competitive regulation</th>
<th>Restricting (individual) entrepreneurial behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation that stimulates entrepreneurial opportunities</td>
<td>Regulation to facilitate sustainable competitive markets</td>
</tr>
</tbody>
</table>

**GE**

- **HS** Allow the insured choice of third-party payer
- Install risk-related adjustments of contributions between third-party payers (to reduce market distortion due to risk selection)

**HS** Allow new/additional services to be included in benefit catalogue
- Require payers to accept all applicants (to lower chance of market distortion due to risk selection)

**HS** Allow differing levels of premiums/co-payments/co-insurance/deductibles
- Mandate annual open enrolment period

**HS** Require financial responsibility of fund (i.e. no retrospective cost cover by government or association of funds)
- Restrict or define conditions for (horizontal) mergers between payers

**HS** Allow/mandate selective contracting
- Restrict (vertical) mergers, acquisitions and running of other health care institutions
- Install supervisory agency(ies) to approve contracts/supervise financial behaviour and stability

**HS** Install risk-related adjustments of contributions between third-party payers (to reduce market distortion due to risk selection)
- A: Require contracts with all willing providers
- Require contracts with all willing providers (if in area of oversupply)

**HS** Require payers to accept all applicants (to enforce right to health insurance)
- C: Mandate community rating or income-related contributions (i.e. not risk-related)

**HS** Mandate annual open enrolment period
- C & Q: Set uniform benefit catalogue/mandate the setting of a uniform benefit catalogue through self-regulatory bodies

**HS** Restrict or define conditions for (horizontal) mergers between payers
- C: Require payers to accept all applicants (to enforce right to health insurance)
- C & Q: Set uniform benefit catalogue/mandate the setting of a uniform benefit catalogue through self-regulatory bodies

**HS** Restrict (vertical) mergers, acquisitions and running of other health care institutions
- S: Regulate maximum expenditure for administrative and overhead costs
- S: Impose actuarial controls, i.e. regulate minimum and/or maximum reserves and types of acceptable investment

**HS** Install supervisory agency(ies) to approve contracts/supervise financial behaviour and stability
- S: Regulate maximum expenditure for administrative and overhead costs
- S: Impose actuarial controls, i.e. regulate minimum and/or maximum reserves and types of acceptable investment

**Abbreviations**: GE = general economy, HS = health sector, A = access, C = social cohesion, P = public health and safety, Q = quality, S = sustainable financing.
Table 1.7 Regulating the entrepreneurial behaviour of hospitals

<table>
<thead>
<tr>
<th>Pro-competitive regulation</th>
<th>Restricting (individual) entrepreneurial behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation that stimulates entrepreneurial opportunities</td>
<td>Regulation to facilitate sustainable competitive markets</td>
</tr>
<tr>
<td>GE European Union regulations on free movement of services</td>
<td>Restriction weakly tied to social objectives that may be unnecessary</td>
</tr>
<tr>
<td>Preferable tax rates/tax exemptions for not-for-profit enterprises</td>
<td>P: National and international (EU/ILO) regulations to protect employees (e.g. working hours or lifting of weights)</td>
</tr>
<tr>
<td>HS Replace activity-unrelated/input-oriented budgets with volume/case-mix-adjusted budgets or contract-based</td>
<td>Include case-mix adjusters into flexible reimbursement system (i.e. restrict adverse selection)</td>
</tr>
<tr>
<td>Explicit reimbursement for formerly cross-subsidized services (e.g. services for uninsured)</td>
<td>A: Stipulate required service hours (e.g. for emergency care)</td>
</tr>
<tr>
<td>Allow retention of surplus/profit (beyond a single calendar year)</td>
<td>Set uniform or maximum price/reimbursement for privately paid services, i.e. for those outside the public benefit</td>
</tr>
<tr>
<td></td>
<td>catalogue or those for privately paying patients</td>
</tr>
<tr>
<td></td>
<td>Restrict the purchase of non-health-care businesses</td>
</tr>
<tr>
<td></td>
<td>Disallow bringing operating surplus forward to next budget year</td>
</tr>
<tr>
<td>Action</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>Allow easy access to capital for infrastructure</td>
<td>Direct governmental accreditation, approval of contracts and/or supervision of financial behaviour/stability</td>
</tr>
<tr>
<td>Allow patients to choose their hospital (with or without the guidance of the general practitioner)</td>
<td>Install supervisory agency(ies) for accreditation (e.g. ANAES in France), approval of contracts and/or supervision of financial behaviour/stability</td>
</tr>
<tr>
<td>Let money follow patient’s choice of hospital (e.g. Sweden, Germany)</td>
<td>C &amp; Q: Waiting time guarantee (e.g. Sweden, Denmark)</td>
</tr>
<tr>
<td>Allow/stimulate contracting of public hospitals to (private) management, possibly based on competitive bidding (e.g. Portugal; Stockholm County, Sweden)</td>
<td>P &amp; S: Disallow advertising of services offered (Germany)</td>
</tr>
<tr>
<td>Allow horizontal and/or vertical mergers</td>
<td>P &amp; S: Require patient co-payments (but exempt poor and vulnerable groups)</td>
</tr>
<tr>
<td></td>
<td>Q: Mandatory accreditation/quality assurance/health technology assessment</td>
</tr>
<tr>
<td></td>
<td>Q: Allow service delivery only according to guidelines and protocols</td>
</tr>
<tr>
<td>Restrict types of service offered (e.g. ambulatory care in Germany)</td>
<td>A &amp; S: Allow (new) hospitals only according to government planning criteria (Germany, Netherlands)</td>
</tr>
<tr>
<td>Regulation that stimulates entrepreneurial opportunities</td>
<td>Regulation to facilitate sustainable competitive markets</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Q: Mandate public disclosure of performance ('league tables')</td>
<td>Q: Set (minimum) standards for staffing numbers and staffing mix (Germany)</td>
</tr>
<tr>
<td>Q: Set (minimum) standards for staffing numbers and staffing mix (Germany)</td>
<td>Q &amp; S: Require referral by lower-level provider (primary and/or secondary ambulatory provider and/or lower-level hospital)</td>
</tr>
<tr>
<td>S: Set uniform or maximum price reimbursement, or require providers and payers to agree on uniform reimbursement schedules (i.e. prohibit price competition)</td>
<td>S: Mandate co-payments (which hospitals may not keep)</td>
</tr>
</tbody>
</table>

Abbreviations: GE = general economy, HS = health sector, A = access, C = social cohesion, P = public health and safety, Q = quality, S = sustainable financing.
Table 1.8 Regulating the entrepreneurial behaviour of ambulatory care professionals

<table>
<thead>
<tr>
<th>Regulation that stimulates entrepreneurial opportunities</th>
<th>Regulation to facilitate sustainable competitive markets</th>
<th>Regulation to ensure achieving social objectives</th>
<th>Regulation weakly tied to social objectives that may be unnecessary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GE</strong> European Union regulations to ensure equal work opportunities for equally qualified non-nationals (free movement of persons)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>European Union regulations on free movement of services</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HS</strong> Allow unregulated establishment of new practices</td>
<td>Direct government accreditation, approval of contracts and/or supervision of financial behaviour/stability</td>
<td>A: Require minimum practice hours (Germany, Netherlands)</td>
<td>Restrict types of service offered by certain types of provider, or create service monopolies for certain types of provider</td>
</tr>
<tr>
<td>Allow additional activities/income besides government/statutory health-insurance-financed services</td>
<td>Install supervisory agency for accreditation, approval of contracts and/or supervision of financial behaviour/stability</td>
<td>A &amp; C: Issue practice permits exclusively/primarily for underserved areas</td>
<td>Regulate maximum practice hours</td>
</tr>
<tr>
<td>European Union regulations to ensure mutual recognition of diplomas of health professionals</td>
<td>Restrict (horizontal) mergers and acquisitions of other practices; allow professionals to own/run one practice only (Germany)</td>
<td>A &amp; S: Restrict new providers according to governmental planning criteria</td>
<td>Set uniform or maximum price/reimbursement for privately paid services</td>
</tr>
</tbody>
</table>
### Table 1.8  Cont.

<table>
<thead>
<tr>
<th>Regulation that stimulates entrepreneurial opportunities</th>
<th>Regulation to facilitate sustainable competitive markets</th>
<th>Regulation to ensure achieving social objectives</th>
<th>Regulation weakly tied to social objectives that may be unnecessary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical autonomy (ability to choose which services to provide)</td>
<td>Require referral by general practitioner (gatekeeping) if specialist is paid fee for service</td>
<td>P &amp; S: Disallow advertising of services offered (Germany)</td>
<td></td>
</tr>
<tr>
<td>Allow patients to choose their physician/health care professional</td>
<td></td>
<td>P &amp; S: Require patient co-payments (but exempt poor and vulnerable groups)</td>
<td></td>
</tr>
<tr>
<td>Let money follow patient choice of physician/health care professional</td>
<td></td>
<td>Q: Allow service delivery only according to guidelines/protocols</td>
<td></td>
</tr>
<tr>
<td>Encourage/mandate market pricing for services paid privately (United Kingdom)</td>
<td></td>
<td>Q: Mandatory accreditation/quality assurance/health technology assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q &amp; S: Require referral by primary care provider (gatekeeping)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>S: Set uniform or maximum price/reimbursement, or require providers and payers to agree on uniform reimbursement schedule</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>S: Mandate co-payments (which providers may not keep)</td>
<td></td>
</tr>
<tr>
<td>Regulation addressing general practitioners specifically (in addition to regulation of ambulatory providers)</td>
<td>P &amp; S: Require patients to register with a general practitioner (to make general practitioner accountable to defined population)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rent public facilities to private general practitioners (below cost if in remote or underprivileged area, e.g. Croatia)</td>
<td>Q &amp; S: Require referral by general practitioner to specialist (gatekeeping)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Regulation addressing dentists specifically (in addition to regulation of ambulatory professionals) | A: Include dental care in publicly financed and/or mandated health care benefits |
| Allow dentists to set their fees (Norway) | A & P: Include dental care for vulnerable populations (e.g. poor, children) into publicly financed and/or mandated health care benefits |

Abbreviations: GE = general economy, HS = health sector, A = access, C = social cohesion, P = public health and safety, Q = quality, S = sustainable financing.
<table>
<thead>
<tr>
<th><strong>Regulation that stimulates entrepreneurial opportunities</strong></th>
<th><strong>Restriction (individual) entrepreneurial behaviour</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GE: General anti-trust/competition laws</td>
</tr>
<tr>
<td>HS: Subsidize/exempt from taxes the development of orphan drugs</td>
<td>HS: Mandatory governmental licences for pharmaceutical manufacturers</td>
</tr>
<tr>
<td></td>
<td>HS: A &amp; S: Allow new pharmacies only according to government planning criteria</td>
</tr>
<tr>
<td></td>
<td>HS: Set uniform or maximum price/reimbursement for privately paying customers, i.e. for drugs outside the public benefit catalogue or to privately paying patients</td>
</tr>
<tr>
<td>Allow open market pricing for pharmaceuticals</td>
<td>Restrict (vertical) mergers, acquisitions and operating of other health care institutions</td>
</tr>
<tr>
<td>Prohibit parallel trade</td>
<td>P: Require customer information; regulate labelling</td>
</tr>
<tr>
<td></td>
<td>P &amp; S: Require patient co-payments (but exempt poor and vulnerable groups)</td>
</tr>
</tbody>
</table>
Abbreviations

GE = general economy, HS = health sector, A = access, C = social cohesion, P = public health and safety, Q = quality, S = sustainable financing.

Encourage consolidation among drug wholesalers

P & S: Prohibit drug advertising for drugs and/or pharmacy services to the general public

Require that pharmacies can be owned only by pharmacists

S: Restrict marketing costs for pharmaceuticals

Restrict (horizontal) mergers; allow pharmacists to own/run one pharmacy only (Germany)

S: Regulate maximum profit margins for pharmaceutical manufacturers (United Kingdom)

Release technical data to generic manufacturers before a drug’s patent expires

S: Set uniform maximum price or reference prices for drugs

Requirements:

- S: Require substitution of generic for brand-name pharmaceuticals
- S: Require hospital formularies
- S: Require office-based physicians and/or drug manufacturers to reimburse insurers for expenses above budget ceilings (Germany)

Release technical data to generic manufacturers before a drug’s patent expires

Encourage consolidation among drug wholesalers

P & S: Prohibit drug advertising for drugs and/or pharmacy services to the general public

Require that pharmacies can be owned only by pharmacists

S: Restrict marketing costs for pharmaceuticals

Restrict (horizontal) mergers; allow pharmacists to own/run one pharmacy only (Germany)

S: Regulate maximum profit margins for pharmaceutical manufacturers (United Kingdom)

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### Table 1.10  Regulating entrepreneurial behaviour in social care

<table>
<thead>
<tr>
<th>Pro-competitive regulation</th>
<th>Restricting (individual) entrepreneurial behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation that stimulates entrepreneurial opportunities</td>
<td>Regulation to facilitate sustainable competitive markets</td>
</tr>
<tr>
<td>GE Preferable tax rates/tax exemptions for not-for-profit enterprises</td>
<td>General anti-trust/competition laws</td>
</tr>
<tr>
<td></td>
<td>P: National and international (EU/ILO) regulations to protect employees (e.g. working hours or lifting of weights)</td>
</tr>
<tr>
<td></td>
<td>P: General regulations for enterprises (environmental, worker safety, consumer protection, etc.)</td>
</tr>
<tr>
<td>HS Create a new financing system for social care, possibly replacing means-tested financing through entitlements</td>
<td>Include case-mix adjusters into flexible reimbursement system (restrict adverse selection)</td>
</tr>
<tr>
<td></td>
<td>A &amp; S: Allow new providers only according to government planning criteria</td>
</tr>
<tr>
<td></td>
<td>Set uniform or maximum price/reimbursement for privately paid services</td>
</tr>
<tr>
<td>Replace activity-unrelated/input-oriented budgets with volume/case-mix-adjusted budgets or contract-based performance-related reimbursements</td>
<td>Restrict horizontal mergers</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Allow patients to choose their provider</td>
<td>Restrict vertical acquisitions by hospitals</td>
</tr>
<tr>
<td>Let money follow patient’s choice of provider (indirectly through contract model or directly by giving cash benefits)</td>
<td></td>
</tr>
<tr>
<td>Allow provider to retain surplus/profit</td>
<td>Allow horizontal and/or vertical mergers among providers</td>
</tr>
</tbody>
</table>
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practitioners became fundholders, and the new arrangement of primary care groups is expected to consolidate the decision-making influence of all general practitioners. In several central European countries, as already noted, much of first-line medical care has become fully private.

Two areas where entrepreneurial forces are relatively strong – social and home care, and pharmaceuticals – have also experienced notable change. Social and home care is, as Forder demonstrates in Chapter 8, perhaps the most dynamic area in the western European health sector at present, with a dramatic increase in experimentation through a large number of entrepreneurial approaches. Most developments appear to involve making public payments of various types (from public funds in Denmark, from social insurance funds in the Netherlands and Germany) that individuals can then use to pay variously vetted public, not-for-profit or, in some instances (Germany), fully for-profit service providers. Pharmaceuticals, not surprisingly given their emergence in the second half of the 1990s as one of the most vexing expenditure issues that national policy-makers confront, have been the subject of both greater entrepreneurialism but also enhanced regulatory efforts to restrict overly aggressive behaviour. As Mossialos and Mrazek demonstrate in Chapter 7, countries are currently moving in a wide variety of often contradictory directions as they attempt to restrain growing pharmaceutical costs in their public and/or publicly reviewed budgets. Yet here, too, an area of European health systems that already has relatively strong entrepreneurial characteristics also saw considerable change during the 1990s.

Interestingly, the sub-sectors with fewer changes in the regulatory/entrepreneurial balance have been those, such as dental care, where entrepreneurial incentives are very strong and those, such as funding, in which, overall, entrepreneurial incentives have been intentionally kept quite weak. Holst et al. (Chapter 11) note that most recent health reforms are not germane to the dental sector, in that many of the proposed entrepreneurial measures are weaker than those already existing in dental care, and they find that there has been little thinking as to whether existing entrepreneurial measures might (or should) be extended further. Funding represents an intriguing case where, quite the opposite from dental care, there is a complex pattern across countries but in which, at least in western Europe, only weak entrepreneurial incentives are tolerated. While tax-funded systems intentionally eschew most entrepreneurial notions regarding funding, SHI-based health systems have found that – for the predominant statutory portion of their funding arrangements – entrepreneurialism directly confronts core social and political policy objectives in ways that make it difficult to accommodate. The major case in point is the Netherlands’ inability to implement the proposals of the 1987 Dekker Report for United States-style managed competition (de Roo 1995; van de Ven and Schut 1995), although a similar if less extreme version can be found in recent German experience (Busse 2000). Sheiman and Wasem, in Chapter 9, strongly suggest that CEE/CIS countries could benefit from adopting this more studied western European approach to introducing entrepreneurialism in their health care funding arrangements.

The upshot seems to be that the extent of change in the regulatory/entrepreneurial balance appears not to be related to the existing entrepreneurial
activity in a particular sub-sector. Rather, it is apparently correlated with particular characteristics of each sub-sector, in particular the extent to which it is perceived to provide a core function and thus should conform closely to broader social and economic policy objectives regarding solidarity, access and cost. Policy-makers in western Europe appear to approach change in these core sectors with both caution and a suitable measure of trepidation.

Having considered the level of entrepreneurial activity as well as the recent extent of change in that level, it remains to explore what is in many ways the most important of the three questions posed. This is the impact of recent changes in entrepreneurial behaviour on productivity and outcomes in the affected health system area. Or, as political scientists put it rather more bluntly, this is the ‘So what?’ question: ‘So what if there’s increased entrepreneurial behaviour?’

Responses to this question typically lag considerably behind, given the necessary lead time required to conduct validated academic studies. If, as noted above, conceptualizing regulation is one of the more controversial substantive issues in social theory, certainly the inability of social science to pronounce rapidly on the consequences of new policy departures has to be one of the most frustrating methodological issues in social policy. As the British economist Tony Culyer (personal communication) has put it, the evaluation mantra runs ‘too early, too early, . . . oops, too late’. There is, furthermore, the dilemma that regulatory interventions often have a preventive purpose, yet it is difficult to calculate how much undesirable behaviour such measures have in fact stopped.

A further set of vexing issues concerns the criteria for assessment. While most commentators consider greater economic efficiency to be valuable, there is less consensus as to whether service effectiveness, access, quality or health gain ought to receive equal consideration. Thus, typically, a study that hails improvements in financial efficiency will ignore the consequences of enhanced entrepreneurial activity along those other dimensions – again complicating objective assessment efforts. Such less-than-complete studies have recently led to hotly contested public debates, not least in the United Kingdom (Bosanquet 2000; Pollock 2000).

Despite these caveats, there is a substantial if not unequivocal body of evidence of the impact of increased entrepreneurial behaviour in the six reviewed health system sub-sectors. Regarding those areas that have seen more change – hospitals and, to a lesser extent, social and home care as well as primary care – the chapters in Part two generally find that the changes associated with increased entrepreneurial behaviour within tax-funded systems have brought greater economic efficiency. Busse et al. (Chapter 6) cite a Swedish study showing that technical efficiency in hospitals improved by 9.7 per cent (Gerdtham et al. 1999). Recent studies in Spain (Andalusia) and Italy are cited that show at least initial improvements in economic efficiency with the establishment of hospitals that are various types of public firms. While, as already noted, evidence about economic efficiency in the United Kingdom has been hotly contested, there are some grounds to suspect a trade-off in that increased productivity generated by hospital-sector reforms may have been largely consumed by greater transaction costs.
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Forder’s (Chapter 8) review of social and home care concludes that, although the reform process is still at an early stage, there is ‘some recent evidence that market arrangements generate lower production costs’. They have also reduced perverse incentives to elect more expensive residential care rather than home care. In primary care, Groenewegen et al. (Chapter 10) conclude that, in tax-funded systems, general practitioners have had more freedom to purchase services and to make budgetary savings.

More broadly, the introduction of entrepreneurial incentives within tax-funded health systems has had considerable impact when it has been combined with patient choice of provider within that system. Anecdotal evidence suggests that, in the hospital sub-sector in Sweden (where patients can choose their hospital) and in the (differently configured) primary care sub-sector in Sweden and the United Kingdom, providers have felt constrained to focus their attention more directly on meeting patient concerns about logistical/scheduling and clinical treatment issues. Put bluntly, publicly operated hospitals and primary care centres in Sweden, and the (now abolished) general practitioner fundholders in the United Kingdom, began to improve publicly provided and/or funded services by treating patients at a higher personal standard. In effect, these reforms introduced the possibility that public-sector and publicly funded institutions can operate at the same high standards typically associated with the private sector, while still maintaining universal access.

The evidence presented in Part two concerning increased entrepreneurial activity is not all positive. Sheiman and Wasem (Chapter 9), addressing funding arrangements in the Russian Federation (and by extension a number of other CIS countries), describe a situation in which entrepreneurialism was unleashed too rapidly and without the necessary countervailing regulation to ensure that core social and economic policy objectives were being met. Ensor and Duran-Moreno (Chapter 5) note that entrepreneurialism without adequate regulation has led, in the CEE/CIS countries in transition, to widespread instances of informal payments and official corruption. Scrivens (Chapter 4) concludes that one reason why governments tend to shift from voluntary high-standard accreditation to mandatory minimal-standard licensure is a strong concern that uncontrolled entrepreneurial freedom will be likely to lead to opportunistic behaviour. Both Groenewegen et al. (regarding primary care) and Forder (regarding social and home care) raise concerns about allowing unbridled entrepreneurial incentives to operate, either because it is incompatible with delivering good service to all citizens (primary care) or because of the skewed character of essential information (social and home care). Similar concerns have been raised by some economists (as noted above) as long ago as Arrow (1963) and as recently as Rice (1998).

The chapters in Part two contain one additional source of evidence about the impact of changes in the regulatory/entrepreneurial balance. In Chapter 3, Rico and Puig-Junoy argue by analogy, reviewing recent experience in deregulating utilities and telecommunications. They conclude that there are two main lessons to be learnt from recent experience in public utility sectors, both of which directly affect the choice of regulatory strategies appropriate to the health sector. One is the importance of moving beyond large-scale or macro-level
contracts to more nuanced institutional-level approaches. This is essential to ensuring that the equity and quality of the delivery system are not negatively affected by the shift from command-and-control to contract-based regulatory arrangements. The second valuable observation concerns timing; specifically, the need to move incrementally in the introduction of newly developed regulatory systems. Both lessons clearly reflect the importance of carefully tailoring new regulations to the emerging entrepreneurial environment as previous command-and-control arrangements are dismantled. This lesson has been reinforced by recent experience with the process of energy deregulation in the United States. Federal data released in mid-2000 show that, in California, one of the country’s largest and most deregulated electricity markets, average wholesale power prices had doubled in the past 3 years (Smith and Fialka 2000). More dangerously, the unwillingness of producers to invest in new capacity has raised the possibility of rolling blackouts during peak mid-summer periods (Berenson 2000). Experts attribute these negative consequences to the problems of transition from regulation to competition, and believe they reflect significant inadequacies in the residual regulatory capabilities of the state.

**Policy-making lessons**

Finding an appropriate and sustainable balance between regulation and entrepreneurial behaviour is a complicated and contentious undertaking. Conceptually, there are strongly divergent opinions among analysts as to what the proper definition of regulation should be and the suitability of regulation as a tool of public policy. Operationally, implementing effective regulatory mechanisms that can help achieve core social and economic objectives requires sophisticated policy-making skills capable of accommodating the multiple intended and unintended consequences that flow from the introduction of restrictive regulatory requirements. Moreover, as Tables 1.6–1.10 demonstrate, regulatory intentions specifically focused on entrepreneurial behaviour can pursue a variety of different, sometimes contradictory, outcomes.

Drawing lessons for future policy-making from recent European experience with the regulatory/entrepreneurial balance is an equally multifaceted endeavour. Opinions diverge and caveats abound. Here, we approach the question of lessons along three related but separate tracks. First, we entertain possible strategies for introducing competition-enhancing regulation, as set out in Chapter 3 by Rico and Puig-Junoy and as put forward in European Union requirements. Subsequently, we present a set of basic ‘rules of the road’, incorporating suggestions from Chinitz (Chapter 2), that attempt to operationalize a broadly ‘public interest’ approach to regulation in the health sector. We then consider the potential impact of several technological advances on future regulatory issues, notably the Internet and the mapping of the human genome, and conclude with comments on the potential future role of social entrepreneurialism.
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Lessons from other sectors

Rico and Puig-Junoy conclude that the design of pro-competitive regulation must reflect both the unique characteristics of each sector and the extent to which that sector produces a social good. They present a three-point methodology to tailor such regulation to an economic sector, focusing on: (1) the particular type of competition to be generated (output competition, competitive tendering, franchise competition and/or competition in capital markets); (2) the contractual issues involved in facilitating the transition from monopoly to competitive production; and (3) regulating prices. The overall message is that, while the process of encouraging entrepreneurialism in the delivery and funding of health services can benefit from experience in other sectors, the content may be too different for any direct transfer to be made.

Rico and Puig-Junoy's views are contrary to several strong tendencies within the European Union to treat the question of encouraging competitive behaviour within the health sector on the same footing as that in any other economic sector. The Treaty of Rome, which established the European Community and was last modified by the Treaty of Amsterdam in October 1997, constructed a 'single market' in the European Community. This market encompasses what is termed the four freedoms of persons, goods, services and capital. Single market regulation clearly has the aim of promoting entrepreneurial opportunities throughout the Union by diminishing or abolishing economic barriers. Article 152 of the Treaty, however, specifically respects 'the responsibilities of the Member States for the organization and delivery of health services and medical care'. This view of a separation between the single market on the one hand and national health systems on the other is complicated, in that the freedom of persons includes the freedom of health care professionals to work in other member states under the same requirements as nationals; the freedom of goods includes the freedom to sell pharmaceuticals or medical devices; and the freedom of services now includes substantial freedom for patients to choose services by health care professionals in another European Union member state (Wismar and Busse 1998, 1999). Pharmaceutical companies, for example, placed substantial pressure on the European Commission in the late 1990s to force member states to accept market-set prices for all drugs sold within their borders (Wold-Olsen 1998).

A particularly vexing dimension of this tension between the single market and the subsidiarity rights of national governments regarding the health sector concerns the legal status of sickness funds and of health sector contracting. Faced with 1990s reforms that sought to encourage competition among sickness funds, the Dutch National Competition Authority has ruled that sickness funds in the Netherlands must be viewed as enterprises (Sheldon 2000). A recent report by the Dutch Raad voor de Volksgezondheyt en Zorg has also suggested that regulations in the Netherlands that restrict open-market pricing of premiums by private health insurers, by mandating cross-transfers to the statutory scheme, may 'not stand the European test'. The report then recommended a redefinition of the role of the European Union and that of its member states in health care to allow 'setting one's own course for the system' (Raad...
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voor de Volksgezondheid en Zorg 2000). Similarly, a recent report written for the European Commission by members of the European Health Management Association raised the possibility that member states with publicly funded or operated health systems may find themselves forced to jettison reforms that introduce entrepreneurial behaviour to preserve their systems’ existing funding and delivery structure (Paton et al. 2000).

Lessons from recent experience

Disputes over the applicability of deregulation and the European Union single market to the health sector underline the increasingly important role that steer-and-channel regulation is likely to play in the short and medium term. Returning to Baldwin’s tripartite discussion of the rationale for regulating, the traditional concern of ‘public interest’ regulation – to guide competitive behaviour into directions consistent with core social and economic objectives that animate national policy – fits well into this picture. For a ‘public interest’ approach to have regulatory teeth, however, it must take on board the insights of the ‘interest group’ perspective as well. Given the evidence and experience presented above about the interconnections between regulatory and entrepreneurial endeavours, as well as the four recommendations made by Chinitz (Chapter 2) regarding ‘good and bad’ regulation, national policy-makers might benefit from considering the four-part ‘rules of the regulatory road’ in Table 1.11 as they select the mix of strategies and tools to apply.

Regulate strategically

Good regulation in the health sector should always have a clear long-term purpose. Just as all large private for-profit corporations use strategic planning to maximize their ability to achieve their objectives, so should public regulators, particularly in dealing with a sector as complex and with as many powerful actors as the health sector (Walt 1998). If regulation is to successfully stimulate entrepreneurial behaviour while still sustaining core social and economic policy objectives, it should be thought through and adopted on a long-term basis.

Regulate complexly

The health sector is one of the most complicated areas that the modern state seeks to regulate. National policy-makers realize that each sub-sector has intricate direct and indirect linkages to other sub-sectors, requiring multiple initiatives to achieve a set policy objective. The perverse consequences of narrowly drawn regulatory efforts in the health sector are the stuff of political science legend. Moreover, powerful health-sector actors arrayed against regulation thrive by seizing on individual regulations one at a time. Setting out a broad integrated
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Table 1.11 Rules of the regulatory road

Regulate strategically
- Regulation is part of strategic planning
- Regulation is a means rather than an end
- Regulation should further core social and economic policy objectives
- Regulation is long-term not short-term

Regulate complexly
- Regulation involves multiple issues simultaneously
- Regulation can combine mechanisms from competing disciplines
- Regulation requires an integrated approach that coordinates multiple mechanisms
- Regulation should fit contingencies of each health system
- Regulation requires flexible public management

No deregulation without re-regulation
- Deregulation requires a new set of regulatory rules
- Re-regulate before you deregulate

Trust but verify
- Regulation requires systematic monitoring and enforcement
- Self-regulation requires systematic external monitoring and enforcement

framework of regulations makes opponents deal with the wider pattern and the policy objectives they seek to achieve.

No deregulation without re-regulation

Any industry leaving behind command-and-control authority for a new life of managerial autonomy will test the permissible policy boundaries. In another context, Williamson (1985) referred to these tendencies as the temptation of opportunism and the limits of rationality. The consequences of such tendencies can be particularly acute in a sector of the economy engaged in providing a complex social good such as health care. The chapters by Rico and Puig-Junoy (concerning deregulation in public utilities) and by Sheiman and Wasem (concerning entrepreneurial incentives in the funding of health care) both describe the importance of putting in place a clear new regulatory framework before dismantling the old command-and-control structure. Smith and Fialka (2000) provide chilling stories about the consequences of inadequate, ineffective and untimely deregulation in the delivery of a far less complex service (i.e. electricity) in California. In recent European experience, Poland found that overly impatient hospital deregulation produced large capital debts, which, subsequently, the Polish state itself has had to discharge (T. Palu, personal communication).

Trust but verify

Regulation without systematic monitoring and enforcement may well be worse than no regulation at all, in that it engenders disrespect and ultimately
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delegitimizes state authority. Particularly in an environment with substantial entrepreneurial incentives, inadequate or absent controls invite disdain for the core social and economic policy objectives that regulation seeks to attain. In practice, this suggests that policy-makers should only promulgate regulations that they know they have the administrative capacity to monitor properly. This requires a balance that preserves adequate cooperation between actors without sacrificing public accountability. This holds equally true in a self-regulatory context, reflecting Baldwin and Cave’s (1999) emphasis on the term ‘enforced self-regulation’. In the CEE/CIS countries, regulation is thus not only a question of designing good regulation but of administrative capacity-building to ensure that those regulations are respected and enforced - a point implicit within Ensor and Duran-Moreno’s own recommendations to reduce corruption.

Lesson-breakers?

Beyond lessons learned from deregulated public utilities and from the health sector, there are two rapidly emerging technological forces that some observers expect to disrupt the existing distribution of authority within health systems. These are, first, the Internet and evolving information technology and, second, the emergence of bioengineering and genomics, especially in the areas of pharmaceuticals and transplantable body parts grown in animals. Although both raise complicated regulatory issues, particularly for the future balance between regulation and entrepreneurialism in health systems, it is unlikely that the regulatory rules of the road just considered will change very much.

The argument that the Internet will force a fundamental restructuring of health care systems is, on the face of it, the more credible. Tremblay (2000) concentrates on the role of the patient, who will have access to vast new sources of information about health and disease treatment, information that will alter what patients expect from their physician and from their health system. The impact of this new information is already apparent, as patients in Wales appear at their general practitioners’ doors carrying pages of computer printout, and English-reading Europeans have access to the advertisements for brand-name pharmaceuticals placed on the Internet by United States drug companies. A broader and potentially even more difficult question concerns the capacity of so-called business-to-business (“B2B”) websites to make fully transparent all contracting and service delivery costs. If a third-party payer (sickness fund, primary care group or county council purchasing unit, to name three) were able, through the Internet, to purchase hospital services from a wide range of providers across Europe and North America, how would that affect both local providers and the regulatory arrangements that national governments use to constrain unacceptable entrepreneurial behaviour? How would such ‘e-commerce’ in health services be dealt with under European Union legislation and judicial decisions?

The probable impact of human genetics on health systems - the second possible lesson-breaker - is less of an unknown. This is because bioengineered
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Pharmaceuticals are already on the market and state regulatory systems have already had to cope with their impact. In this instance, the challenge is not to the structure and authority of the health system but to its available funding. Bioengineered pharmaceuticals also tend to emphasize the curative and individual-focused rather than the preventive and population-based aspects of health policy-making. While the recent rise in pharmaceutical costs associated with the introduction of new ethical compounds has strained health sector budgets all across Europe, the response by national governments has been instructive. As Mossialos and Mrazek suggest in Chapter 7, regulations are becoming increasingly sophisticated in the range of tools they are applying. Far from overwhelming the existing regulatory apparatus, the recent upsurge in cost has given new life to the regulatory enterprise across Europe. Whether and to what extent the regulatory response will be successful in containing rising costs is less important here than the fact that this new challenge has not overwhelmed the existing regulatory ramparts.

This observation regarding human genetics brings us back to the challenge of the information economy. Solutions with regard to the new role of patients will probably reflect two realities. One is that publicly employed physicians can also search out new clinical information on the net, so as to be as well informed as their patients about new treatments. The second is that, as health systems become more flexible by increasingly decentralizing decision-making both to funders and to providers (for example, the purchaser-provider split in tax-funded countries), these new decision-makers will be able to move more rapidly to incorporate new procedures and treatments.

The challenge presented by the emergence of B2B e-commerce in the health sector is a more difficult one for existing, nationally based regulatory authorities. Perhaps the most useful observation that can be made at the time of writing (September 2000) is that it is still highly likely that, when the cyberdust settles, the same regulatory rules of the road will apply. Their mode of application is likely to change, but their focus and methodology will probably be strikingly familiar. The only alternative is to imagine a future in which governments can no longer insist that health-sector actors are bound by the state’s core social and economic policy objectives. To make such a case, one is no longer suggesting that the health sector will be fundamentally changed, but rather that the existence of the state as a political creature will be fundamentally changed. Suffice it to say that such a debate extends beyond the framework of this volume.

**Concluding observations**

There is little doubt that the test of wills between regulators and entrepreneurs in the health sector will intensify in the future. There will probably also be a slower but steady growth in the number of social entrepreneurs, operating inside the boundaries of the public sector but importing a variety of private-sector concepts and incentives. As policy-makers become more comfortable with the probable outcomes that they can achieve by balancing specific market-oriented mechanisms with targeted regulatory requirements, they are likely
to be more willing to allow those mechanisms to play a greater role within publicly operated and publicly accountable health systems. Much as Drucker (1985) desired and, in the health sector, van der Grinten (1999) has proposed, there should be a noticeable increase in what the latter has termed 'social entrepreneurialism'. This middle territory between purely bureaucratic public and purely for-profit private may itself blur the public-private boundaries by incorporating, as in the Netherlands, elements of not-for-profit private in partnership with independently managed public-sector organizations. Here, too, the regulatory challenges will be considerable, and successful outcomes will be contingent on the evolution of systems of subtly targeted regulatory arrangements.

One potential regulatory framework that has yet to be adequately explored in the health sector is the application of the notion of independent regulatory agencies. Although, as currently configured, these are not as yet appropriate to play a substantial role in regulating health-related entrepreneurial behaviour, the generally positive experience with them in reconfiguring the balance of stability and competition in the regulation of public utilities and telecommunications suggests that this may be an area for future creative thinking.

One can also anticipate that, as the overall entrepreneurial level increases within health systems, the range, scope and capacity of state regulation will have to increase with it. The chapters in Part two may help policy-makers to consider which health system sub-sectors are currently over-regulated and which may be under-regulated. Once again, as noted elsewhere (Saltman and Figueras 1997), an increase in market-oriented activity in the health sector necessarily generates an increase in the state-based regulatory response. It appears safe to predict that, while the methodology of regulation will be improved and refined and new regulatory tools will be developed, tested and adopted, the basic process of regulating - the regulatory rules of the road - will remain as important as ever. The challenge to policy-makers will thus be to concentrate their energies on designing a better framework with which to conduct that supervision.

References


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