

MOVING IN FROM THE
FRINGES:
THE REGULATION OF
COMPLEMENTARY AND
ALTERNATIVE MEDICAL
PRACTITIONERS IN THE UK

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ABSTRACT

Taking the cases of five complementary therapies in the United Kingdom, the study seeks to explain why some complementary medical practitioners are statutorily regulated while others remain unregulated. It also asks why regulation has taken the form that it has.

The analytical framework used draws on sociology, economics and political science. The study examines whether statutory regulation is best explained as the result of the mobilisation of complementary medical practitioner groups, actions by the state, or interactions between individual policy actors. It tests the explanatory value of demand theories of professionalisation, supply theories of professionalisation, and personal policy network analysis. It also examines the role of ideas in shaping policy.

While practitioner groups in all five therapies were professionalised not all actively pursued statutory regulation. In the cases of osteopaths and chiropractors mobilisation by practitioner groups appears to explain their success in gaining statutory regulation. The state's concern to regulate risk appears to have been crucial in the decision to introduce statutory regulation for acupuncturists and herbalists. In all cases, individual policy entrepreneurs and policy advocates, including HRH the Prince of Wales, played a crucial role in shaping the policy process. The medical model of professional self-regulation dominated policy ideas. Alternative regulatory models were seldom debated.

The study discusses the implications of the findings for the future of professional regulation of CAM practitioners and healthcare professionals generally. It concludes by suggesting that despite its limitations personal policy network analysis might usefully be applied in other contexts.

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LIST OF ABBREVIATIONS

AACP	Acupuncture Association of Chartered Physiotherapists
ARWG	Acupuncture Regulatory Working Group
ATCM	Association of Traditional Chinese Medicine
BACc	British Acupuncture Council
BAWA	British Academy of Western Acupuncture
BCA	British Chiropractic Association
BMA	British Medical Association
BMAS	British Medical Acupuncture Society
BNA	British Nurses Association
BOA	British Osteopathic Association
CA	Consumers' Association
CAM	complementary and alternative medicine
CHRE	Council for Healthcare Regulatory Excellence
CORH	Council for Organisations Registering Homeopaths
CPSM	Council for Professions Supplementary to Medicine
EHPA	European Herbal Practitioners Association
EU	European Union
GCC	General Chiropractic Council
GDC	General Dental Council
GMC	General Medical Council
GOsC	General Osteopathic Council
GP	general practitioner
HMRWG	Herbal Medicine Regulatory Working Group
HPC	Health Professions Council
ICM	Institute for Complementary Medicine
MCA	Medicine Controls Agency

MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NMC	Nursing and Midwifery Council
PCT	Primary Care Trust
POPAN	The Prevention of Professional Abuse Network
TCM	traditional Chinese medicine
UK	United Kingdom
UKCC	United Kingdom Central Council on Nursing, Midwifery and Health Visitors
WHO	World Health Organization

NOTE ON TERMINOLOGY

The field of CAM policy is littered with acronyms to be deciphered (see list of abbreviations). To make things more confusing several organisations which feature here have changed name during the period of study. This can make it difficult for the reader to follow the involvement of groups in the policy process over time. This brief introductory note describes these name changes and explains the terminology adopted in the study which follows.

The Prince's Foundation for Integrated Health began life as the Foundation for Integrated Health following the work of The Prince of Wales's Initiative on Integrated Medicine. It has since changed its name to the Foundation for Integrated Medicine, the Prince of Wales's Foundation for Integrated Health and most recently to The Prince's Foundation for Integrated Health. Here I refer to it as the Foundation for Integrated Health throughout or simply the Foundation.

The Prevention of Professional Abuse Network (POPAN) has rebranded and is now called Witness: against abuse by health & care workers. This name change occurred after the main study period therefore POPAN is used throughout.

The Council for Professions Supplementary to Medicine (CPSM) was abolished and succeeded by the Healthcare Professions Council (HPC) in 2002 following the Health Professions Order 2001. Depending on the period under scrutiny the appropriate title is used. The Council for the Regulation of Healthcare Professionals was created by the NHS Reform and Health Care Professions Act 2002 following the recommendations of the Bristol Royal Infirmary Inquiry (Bristol Royal Infirmary Inquiry, 2001). It was almost immediately re-branded as the Council for Healthcare Regulatory Excellence (CHRE) partly to avoid confusion with the HPC. It is referred to by this latter title throughout.

The Department for Education and Employment established a network of national training organisations to establish standards for skills and qualifications. Healthwork UK was appointed in 1998 by the government to work in the health sector and included a specific remit to support the needs of CAM practitioners (Department of Health, 2000b). Healthwork UK along with other national training organisations was disbanded around 2002 to be replaced by Sector Skills Councils. Skills for Health was established in April 2002 and licensed by the Secretary of State for Education and Skills as the UK Sector Skills Council for health in May 2004. It is funded through the four UK health departments, the Sector Skills Development Agency, the Education Act Regulatory Bodies and NHS,

independent and voluntary employers. Many of the responsibilities of Healthwork UK (and also some of the staff) transferred to Skills for Health including responsibility for national occupational standards and other competency frameworks (Lane, 2006). Given these are distinct organisations the respective titles are used.

Over a longer period of time, CAM practitioner groups have changed names frequently, sometimes following a merger or split with another part of the profession. For the most part the name they are currently known by is used. Table 4.3 gives an overview of the main organisations and their incarnations for the five therapies studied here.

Government departments are reorganised at regular intervals. The Department of Health and Social Security was split into its component parts on 25th July 1988. Since then the Department of Health has avoided any departmental mergers but has undergone major internal reorganisation. Devolution has changed its scope. Responsibility for health services is now devolved to the Welsh Assembly and to the Scottish Parliament. Professional regulation however is reserved to Westminster and therefore applies to the United Kingdom as a whole (Greer, 2004). For example consultation on recent regulatory proposals has been conducted by the Department of Health in England on behalf of the four UK health departments. Here the analysis is of regulatory policy for CAM practitioners in the UK, though as with many policy networks it is Anglo-centric.

1 INTRODUCTION

1.1 Background

The history of medicine is the story of a dynamic and changing set of healing practices. The definition of medicine and the state's role in it have changed over time and differ between cultures (Porter, 1989; Jütte, 1996). The introduction of statutory regulation of the medical profession in western Europe in the 19th century secured the position of doctors and their control over medical practice. The boundaries between conventional medicine and alternative medicine created at that time were largely a result of the successful mobilisation of doctors' interests. Unlike their counterparts in many other western European countries alternative medical practitioners in the United Kingdom (UK) continued to practise legally but were not regulated by the state. Over the course of the 20th century nurses and other health care professionals gained statutory recognition. Only towards the end of the century did any complementary and alternative medical (CAM) practitioners gain similar state sanctioned self-regulating powers.

There is a wide range of terminology used to describe different approaches to medicine. Complementary medicine is commonly used but other synonyms such as alternative, traditional, unconventional, holistic, parallel, eastern, or folk medicine are also found. Their antonyms include biomedicine, orthodox, conventional, allopathic, or scientific medicine. The term 'complementary medicine' is a relatively recent designation for a range of healing practices that have in some cases been practiced for hundreds of years. Prior to the mid-20th century such therapies were often referred to as 'primitive medicine' in colonial settings and 'fringe' or 'marginal medicine' in western contexts.

Some terms carry additional meaning in that they are utilized either by proponents or critics. The term 'complementary medicine', which has become increasingly used since the 1980s, emphasizes the use of treatments as an adjunct to or supplementary to conventional medicine. The term 'alternative' medicine suggests its use substitutes for and excludes utilization of conventional medicine. The term 'complementary and alternative medicine' (CAM) is widely used in scientific and policy-related discourse and has been defined as "a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system" (World Health Organization, 2000). The term CAM will be used throughout this study.

Popular demand for CAM therapies is high and rising. The number of people training in and practising CAM therapies is growing, and there is increased interest among conventional health care professionals in the integration of CAM therapies within their own practice. In this environment policymakers have been prompted to question the adequacy of existing regulation (or lack of it). The policy response in the UK has been to introduce statutory self-regulation for certain CAM practitioners and to encourage robust systems of voluntary self-regulation for others. The model of regulation adopted is similar to that introduced for doctors in the 19th century: a professionally led council that sets standards and registers practitioners with powers to sanction registrants who fail to meet ethical and practice standards. Given CAM's own ambivalence (at times antagonism) to orthodox medicine it is perhaps surprising that they should be regulated according to institutional arrangements developed for the regulation of the medical profession – especially as those institutional arrangements themselves are being challenged.

1.2 Research questions

The focus of this project stems primarily from my own interests in the politics of health care, regulation and international comparisons of health care markets and systems. I am interested in how CAM practitioners have moved in from the fringes of medicine, where they operated for much of the 20th century, to occupy a more central position in modern health care policy. I wish to explain why some groups of CAM practitioners have gained statutory regulation. This study differs from much of the existing literature on complementary and alternative medicine (CAM), which is dominated by studies focused on the efficacy and effectiveness of therapies, consumer utilisation and health beliefs, the micro level of practice and intra-professional ethics (see Lew-Treweek, Heller et al., 2005 for a collection of papers on CAM).

The focus of this study is the process of policy-making that has led to these regulatory developments. The main research question to be addressed in this study is:

- Why has the regulatory process for CAM practitioners in the UK taken the form that it has?

In particular,

- Why are some CAM therapies statutorily regulated and others not?
- What model of regulation is used to regulate CAM practitioners in the UK, and why was this model chosen?

The statutory regulation of osteopaths and chiropractors, the proposals for statutory regulation of herbalists and acupuncturists, and the progress towards voluntary regulation by homeopaths are analysed in this study in an attempt to answer these questions. Action has been taken recently to regulate CAM products following the EU Directive on Traditional Herbal Medicinal Products (2004/24/EC). There continues to be policy debate about the safety and efficacy of CAM products in the UK parliament (Hansard, 26 October 2006). It is practitioners not products, however, that are the focus of this study.

The study analyses oral and written evidence to the House of Lords Select Committee on Science and Technology on Complementary and Alternative Medicine, official government publications, submissions to the Department of Health consultation on proposals for the statutory regulation of acupuncture and herbal medicine, reports of the Regulatory Working Groups and other published documents by key stakeholders. These documentary data are supplemented by in-depth semi-structured interviews with key individuals. Chapter 6 sets out in greater detail the methodology employed.

Most studies of regulation in other sectors of the economy have adopted an economic perspective, analysing how governments intervene in the market for particular goods and services. There has, however, been increasing recognition of the value of multidisciplinary approaches and their application to the study of regulation (Baldwin and Cave, 1999). They are often better able to answer those questions that are not traditionally the subject of regulation research, such as why a particular measure was introduced. Public opinion and private interests have been identified as key drivers of regulation alongside market failure (Hood, Rothstein et al., 2001). In contrast, the professional regulation literature is mainly sociological in approach, and has focused on professional identity and authority and how this is constructed. Accordingly the study adopts a multidisciplinary approach to the analysis of professional regulation. It applies concepts from political science, economics and sociology to an analysis of the regulatory process.

1.3 Outline of the study

Following this introduction, chapters 2-4 set out the context for the study. Chapter 2 describes the market for CAM in the UK. It depicts a rapidly expanding market in both CAM products and practitioner services, and highlights the implications for regulation. Self-regulation is just one of many options available to policymakers. Chapter 3 reviews a range of regulatory approaches and how they might apply to CAM practitioners. It highlights the key features of a number of different regulatory approaches that are used in other countries to regulate CAM practitioners. Contrasting approaches have emerged

internationally for historical and cultural reasons. Chapter 4 describes the historical background to professional regulation in the UK from the late 19th century onwards. It describes key events in the professionalisation of CAM practitioners prior to the 1990s, as well as highlighting examples of other health care professionals.

Before presenting the results of the empirical analysis Chapter 5 reviews the theoretical literature and sets out the analytical framework to be used. Sociological theories about the nature of professionalisation, the economic literature on occupational closure, and political science theories of the policy process are reviewed. In response to an emergent theme of risk, the literature on risk regulation is also included.¹ The chapter briefly reviews concepts used in other empirical studies of the professionalisation of CAM practitioners. The literature is organised into demand theories of professionalisation, which argue that professionalisation is the result of mobilisation by occupational groups, and supply theories, which argue that professionalisation is a result of state actions. Each are reviewed for their potential to provide a framework for explaining the regulatory process. The chapter concludes by presenting the analytical framework to be employed in the study. Chapter 6 describes the methodology for the study. It justifies the use of qualitative methods for answering the research questions and explains the selection of therapies on which the study focuses. It describes the selection of documents and interviewees and how qualitative software was used during the analytical process.

The empirical analysis is presented in Chapters 7-10. The analysis focuses on the regulatory process surrounding five CAM therapies: acupuncture, chiropractic, herbal medicine, homeopathy, and osteopathy. Chapter 7 uses demand theories of professionalisation to explain why some CAM practitioners have achieved statutory regulation. It analyses whether CAM practitioner groups were organised and mobilised in pursuit of statutory recognition and, if so, what motivations lay behind these demands.

Chapter 8 uses the supply theories of professionalisation to examine the role of the state in determining which CAM therapies are granted statutory self-regulating powers. It identifies the strategies that the state has used to regulate these groups and analyses the arguments used to justify the regulation of CAM practitioners.

In order to explore more fully the dynamics of the regulatory process Chapter 9 uses an adaptation of policy subsystem analysis to explain why certain therapies are statutorily regulated. It examines the role of individuals in shaping regulatory policy, including state actors, representatives of CAM practitioner groups, consumer representatives, academics

¹ The scope of the review and the final analytical framework were partly informed by preliminary analysis of the data.

and representatives of orthodox medicine. Use is made of policy maps that depict the affiliations of and inter-relationships between individuals at different stages in the regulatory process to identify 'policy entrepreneurs' who have influenced the process.

Chapter 10 examines the *type* of regulation that has been introduced for CAM practitioners and seeks to explain why this model has been adopted. It examines the debates among CAM practitioners, the state and other members of the policy network about how to regulate, and the functions and structure of regulatory bodies. The concept of policy paradigms is used to explain why certain policy ideas dominate.

Chapter 11 discusses the implications of the empirical findings for wider policy discussions about the future of professional regulation. It also discusses the strengths and limitations of the analytical approach, and considers its wider application to other health policy research. The chapter draws together the conclusions of the study and highlights areas for further research.

1.4 Why is the regulation of CAM practitioners an important issue?

Growth in public demand for, and use of, CAM products and services has certainly been an important factor in the growth of research and policy interest in CAM. There is a large market for CAM therapies in the UK (Thomas, Nicholl et al., 2001; Thomas and Coleman, 2004) and demand has been increasing worldwide (Eisenberg, Davis et al., 1998; Institut für Demoskopie Allensbach, 2002). This is likely to continue as the prevalence of chronic diseases, for which CAM is believed to offer relief, rises (Long, Huntley et al., 2001). Although the majority of CAM services are currently paid for by patients and provided in the private sector (Thomas, 1995; Thomas, Nicholl et al., 2001), there is increasing pressure to make CAM therapies more widely available through the NHS (Smallwood, 2005). Public funding of CAM therapies is likely in future as further research into the efficacy of CAM becomes available (Vickers, 2000), and attitudes of medical practitioners change (Lewith, Hyland et al., 2001; Schmidt, Jacobs et al., 2002).

The regulation of CAM is already the subject of policy and research activity, though there has been more attention on products than on practitioners (Shaw, 1998; Standing Committee on Health, 1998; Ernst and Dixon, 2004). The World Health Organization (WHO) has published numerous reports on the legal status of herbal medicines worldwide (World Health Organization, 2001; World Health Organization, 2005), and published its own Traditional Medicine Strategy in 2002 (World Health Organization, 2002). The European Union (EU) introduced a Directive on Traditional Herbal Medicinal Products

(2004/24/EC) which came into force in Member States on 1st November 2005. A separate Directive governs the licensing of homeopathic medicinal products (92/73/EC). In the United Kingdom the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for licensing medicines including herbal medicines. It also monitors adverse drug reactions through the Yellow Card Scheme which was extended to include unlicensed herbal products in 1996.

Growing interest in the regulation of CAM practitioners is likely given the wider debate about the future of health care professional regulation in the UK. Changes in the health care workforce and the need for greater flexibility in the skills of and tasks performed by health care practitioners have exposed the limitations of existing structures of regulation (Department of Health and Royal College of General Practitioners, 2002). Yet it is the high profile failures in the system that have precipitated discussions about reform. In particular, the events at Liverpool Children's Hospital in Alder Hey and the Bristol Royal Infirmary, the publicity surrounding the arrest and conviction of Dr Harold Shipman, and the activities of Rodney Ledward and Richard Neale eroded public confidence in professional self-regulation (Irvine, 2003). The reports of the Bristol Inquiry (Bristol Royal Infirmary Inquiry, 2001) and the Shipman Inquiry (Department of Health, 2004b) have challenged the approach to professional self-regulation, calling for greater public scrutiny and independent disciplinary procedures. Government reforms are still to be finalised following the reports of two internal reviews (Chief Medical Officer of England, 2006; Department of Health, 2006c).

Professional regulation is also under discussion in Europe, where a revised Directive on mutual recognition of professional qualifications has been passed (2005/36/EC). The requirement under EU law that there should be free movement of professionals within the EU means that professional regulation is no longer solely a matter for nation states. Differences in the legal status of CAM practitioners between Member States mean that free movement and the right to establish a business are not currently upheld for CAM practitioners. Although there have been no legal challenges to date, the European Court of Justice could be asked to rule on such matters in future. Previous interpretations of EU law have posed significant challenges to national self-determination or subsidiarity in regard to health care policies (Mossialos and McKee, 2002).

1.5 Aims and objectives

The main aim of the study is to present an account and an explanation of why the regulatory process for CAM in the UK has taken the form that it has since 1990. The

results of the empirical analysis will add to a growing body of research on professional regulation (Davies, 2004) and CAM (Heller, Lee-Treweek et al., 2005). The study uses an innovative analytical approach, 'personal network analysis'. Most health policy research focuses on issues of 'high politics' involving Ministers and senior civil servants, where the interests of the orthodox medical profession often dominate. Here I examine the policy process in a small, low visibility sub-sector where interest groups are in a state of flux, where individuals play a central role, and where there are only a few state actors involved (generally mid- to low-ranking civil servants).

It is expected that the findings of the study will inform policy discussions about how to regulate CAM practitioners and the future of health care professional regulation more generally in the UK. An enhanced understanding of regulatory developments in relation to CAM practitioners in the UK could also inform debates on this subject within the EU and elsewhere.

2 THE MARKET FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

2.1 Introduction

There is a popular perception that use of complementary and alternative medicine (CAM) grew rapidly during the 1990s. Although there are no longitudinal studies to prove this, cross sectional data presented below indicate this to be the case. Rising public demand and the associated growth in the number of people practising these therapies has brought new regulatory challenges. Before going on to describe the developments in regulation and analyse the regulatory process in later chapters, we begin with an overview of the market for CAM in the UK.

Section 2.2 describes the prevalence of use of CAM and summarises key demographic variables of those who use it. Conventional health care in the UK is mostly funded through general taxation and provided by public providers within the National Health Service (NHS), though there is growth in private provision. Section 2.3 describes the extent to which CAM services are publicly funded and the availability of CAM through the NHS.

This study focuses mainly on those people who provide CAM therapies. Section 2.4 provides an overview of the different types of practitioners, together with estimates of their number. The chapter concludes by highlighting the regulatory issues that the growth in CAM raises for policymakers.

2.2 Who uses CAM?

The British public's perception is that CAM use is increasing (78% of respondents in a BBC poll) (Ernst and White, 2000) and yet there is no systematic research evidence to support this view. Despite the fact that there have been numerous population surveys of CAM use, none has been conducted using a consistent survey instrument to give a trend over time. Studies in the United States found an increase in one-year prevalence of use between 1991 and 1997 (33.8% vs. 42.1%) (Eisenberg, Davis et al., 1998) but similar prevalence levels in 1997 and 2002 (36.5% vs. 35.0%) (Tindle, Davis et al., 2005). The Sub-Committee on Complementary and Alternative Medicine of the House of Lords' Select Committee on Science and Technology reported that it had "heard much evidence to the effect that we are now experiencing a rapid increase in the use of CAM across the Western

World [sic]" whilst acknowledging that much of the specific information did not refer to the UK (House of Lords Select Committee on Science and Technology, 2000a, para 1.14).

There have been several systematic reviews, population surveys, and surveys of specific patient populations on use of CAM. There has even been a review of unpublished studies (Ong and Banks, 2003). The following section summarises the results of studies published since 1980 and identified in PUBMED,² in order to present a fuller picture of use of CAM.

2.2.1 *Systematic reviews*

The published systematic reviews are international in scope. Harris and Rees (2000) identified 12 studies of CAM use among the general population of which only Yung, Lewis et al. (1988) and Thomas, Fall et al. (1993) surveyed a UK sample (Harris and Rees, 2000).

Yung, Lewis et al. (1988) analysed data from the 1986 Cardiff Health Survey, a self completed questionnaire sent to a random sample of the electoral register (n=4268). 2.6 percent of the sample reported having used CAM (not on the NHS) during the last year (Yung, Lewis et al., 1988). Thomas, Fall et al. (1993) surveyed a random sample of the electoral register as part of a pilot study in 1993 (n=676). They estimated that 8.5 percent of the population had visited a CAM practitioner in the previous 12 months whilst a quarter had used an over-the-counter remedy during the same period (Thomas, Fall et al., 1993).

Ernst (2000) identified a total of 12 studies up to and including 1997 only two of which were of UK populations (Ernst, 2000). Vickers (1994) reports the results of Thomas, Fall et al. (1993) (see above). Emslie, Campbell et al. (1996) conducted a postal questionnaire of a random sample of the adult population in the Grampian Region of Scotland (n=500). 29 percent of respondents reported ever using at least one of eight named therapies. Ten percent reported having used reflexology whilst as many as 35 percent had used osteopathy (Emslie, Campbell et al., 1996).

One systematic review of the prevalence of use by children was identified (Ernst, 1999). This included one study from the UK which found that 21 percent of parents of children attending paediatric clinics in South West England (n=521) had used CAM (Simpson, Pearce et al., 1998). The prevalence was lower among parents in the community sample than in the hospital sample (15% vs. 25%).

² The following search terms were used: MESH headings 'complementary therapies' and 'Great Britain' and any field containing 'utili*' OR 'use'. The abstracts of original articles were reviewed to identify studies which reported prevalence estimates either in the general population or among specific patient groups.

A systematic review of usage of complementary therapies in rheumatology identified four studies in the UK. Overall prevalence of CAM use among rheumatology patients was high, ranging from 60 percent to 71 percent (Ernst, 1998b). These figures included use of supplements and diets.

A systematic review of use of CAM by cancer patients identified two studies in the UK (out a total of 26 studies). The prevalence of use of CAM reported was 32 percent and 16 percent in the two UK studies published in 1993 and 1994 respectively (Ernst and Cassileth, 1998).

2.2.2 *Other population surveys*

A further five studies were identified which reported results of population surveys that asked about use of CAM. Murray and Shepherd (1993) found that 41 percent of inner London general practice patients who responded to a postal questionnaire had used CAM in the past ten years (n=372). The most common therapies used were osteopathy (14%), homeopathy (13%), massage (11%), acupuncture and herbalism (both 9%) (Murray and Shepherd, 1993).

Ong, Petersen et al. (2002) report the results of a survey of adults aged 18-64 years in four southern counties of England in 1997 (n=14,868). 7.8 percent of respondents had consulted a CAM practitioner in the previous three months. Women were significantly more likely to report visiting a CAM practitioner than men (9.5% vs. 5.5%) and CAM users were more likely to be from non-manual social classes. Use was lowest among those under 35 years old and highest among those aged 35-44 years (9.2%) (Ong, Petersen et al., 2002).

Ernst and White (2000) report the results of a national telephone survey with a random sample of adults in 1999 (n=1204). 20 percent of respondents reported using CAM at least once during the last year. Chiropractic was the least popular therapy and herbal medicine the most popular (6% vs. 34%). CAM use was highest among women (59%), employed people (63%), 35-64 year olds, and higher social classes. There was regional variation with the lowest prevalence in the West Midlands (16%) and the north of England (11%) and the highest in Wales (32%) and the south east of England (23%) (Ernst and White, 2000).

Thomas, Nicholl et al. (2001) report the results of a survey of a geographically stratified random sample of adults in England in 1998 (n=5010). 28.3 percent reported ever visiting a practitioner of one of six named therapies. 10.6 percent of respondents reported doing so within the last year with a mean of 4.5 visits. This is equivalent to 4.2 million adults making 22 million visits in 1998. Consistent with previous research they found use was higher among women (Thomas, Nicholl et al., 2001).

The most recent estimates of CAM use in the UK were obtained from data collected in March 2001 from the Omnibus Survey (a regular multi-purpose survey carried out by the Office for National Statistics) (n=2761). Thomas and Coleman (2004) estimate that ten percent of adults had visited a CAM practitioner to receive treatment in the past 12 months. An estimated 6.5 percent of adults had used one of the five therapies examined in this study. In contrast to previous studies men and women used therapies in equal proportions. The study also reported that the majority of CAM use was for an illness or condition for which conventional medical advice had previously been sought (62%) (Thomas and Coleman, 2004).

2.2.3 *Sub-population surveys*

From a patient safety perspective it is important to understand whether patients who consult conventional health care also use CAM therapies. There have been numerous surveys of CAM use among specific patient populations in the UK. Studies have analysed use among children in secondary and tertiary hospital settings (Johnston, Bilbao et al., 2003; Molassiotis and Cubbin, 2004; Cincotta, Crawford et al., 2006; McCann and Newell, 2006), attendees in general practice (Featherstone, Godden et al., 2003), members of the National Asthma Campaign (Ernst, 1998a), chronic pain sufferers (Haetzman, Elliott et al., 2003), patients attending general rheumatology and orthopedic (non-fracture) clinics (Chandola, Young et al., 1999), peri- and post-menopausal women (Vashisht, Domoney et al., 2001), cancer patients (Rees, Feigel et al., 2000; Lewith, Broomfield et al., 2002; Harris, Finlay et al., 2003; Scott, Kearney et al., 2005), patients presenting at tertiary clinics with Systemic Lupus Erythematosus (Moore, Petri et al., 2000), and dermatology patients (Nicolaou and Johnston, 2004).

Prevalence estimates reported in these studies ranged from 25 percent to 59 percent. For example 28 percent of patients attending a musculoskeletal clinic had used CAM, the most popular treatments being acupuncture, homeopathy, osteopathy and herbal medicine (Chandola, Young et al., 1999). 59 percent of asthma patients recorded some use of CAM, with those having more severe asthma reporting higher use than those suffering less severely (Ernst, 1998a). 48 percent of patients with lupus reported use of at least one CAM therapy in the past six months, with relaxation, massage, herbal medicine and lifestyle diets the most common (Moore, Petri et al., 2000). 22.4 percent of women diagnosed with breast cancer had consulted a CAM practitioner in the past 12 months, while 33.2 percent reported using an over-the-counter remedy, the most common therapies were massage/aromatherapy, chiropractic/osteopathy, relaxation/yoga/meditation and spiritual healing (Rees, Feigel et al., 2000).

These surveys indicate that the use of CAM therapies by patients in receipt of conventional medicine is common.

2.2.4 Discussion

Existing research does not verify that there has been an increase in demand for CAM services. What it does show is that an estimated ten percent of the general population visit a CAM practitioner at least once in a given year and around six percent of the population use acupuncture, chiropractic, herbal medicine, homeopathy, or osteopathy.

Levels of use vary within the population. Greater use of CAM in higher socio-economic groups may reflect the cost of therapies and their lack of availability on the NHS (see below). It may also reflect differences in health beliefs and preferences among different social groups. The recent finding that men are as likely to use CAM as women (Thomas and Coleman, 2004), if not due to differences in study design, could be explained by changing social attitudes among men towards health in general and CAM in particular. CAM use is highest among the middle aged. If this is a cohort effect we might expect CAM use to rise in future among the older age groups.

Many of the published surveys were conducted in NHS clinics, indicating a growing interest and concern within conventional health care about the use patients are making of CAM. Conventional health care providers are being encouraged to elicit information about use of CAM therapies when taking medical histories, and research into the interaction effects is being conducted (see for example Cupp, 1999; Thompson Coon, Pittler et al., 2003). Systematic research on the utilisation of CAM by different patient groups could be used: (i) to identify priority areas for research on efficacy of CAM treatments versus conventional treatment; (ii) to indicate where research on interaction effects is needed; (iii) to help target educational programmes for conventional health care providers, and; (iv) to identify areas where integrated services might be most fruitfully developed.

The popularity of CAM has also led to demands that it should be made more widely available on the NHS. The next section looks at how CAM is currently paid for and the extent to which it is available through the NHS.

2.3 How are CAM services financed?

There are at least four main sources of health care funding that can be identified: public funding (e.g. through general taxation or national insurance contributions), out-of-pocket spending, private health insurance premiums, and charitable or voluntary donations. Unlike most other types of health care, CAM therapies are predominantly privately financed.

2.3.1 Public financing

Within the NHS some CAM therapies such as homeopathy and acupuncture are directly provided, while others such as osteopathy and chiropractic are privately provided but may be funded through local purchasing arrangements. Herbal medicine is almost exclusively private, usually paid for by the consumer.

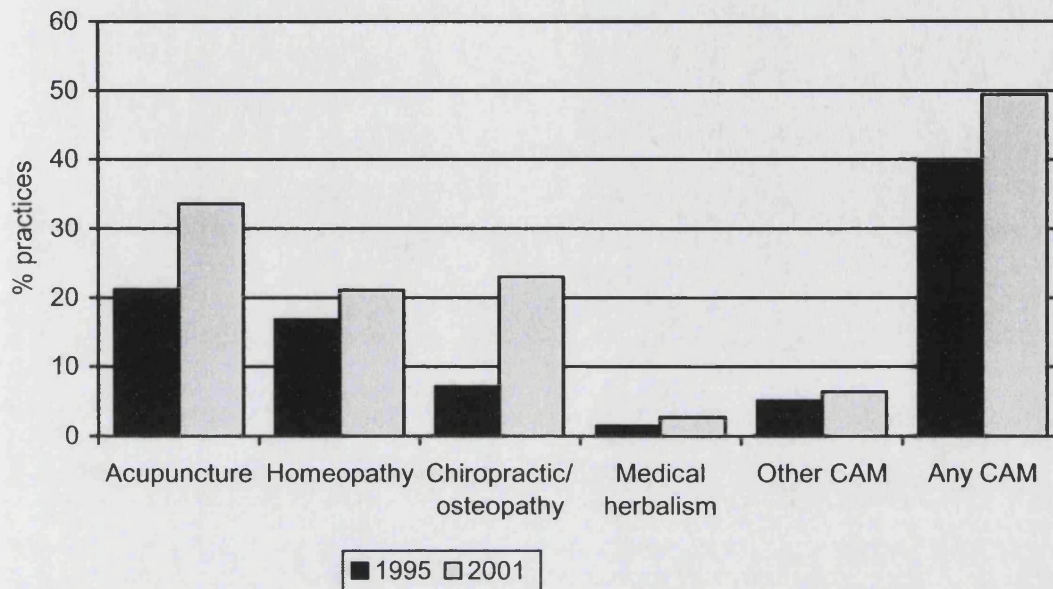
There are currently five homeopathic hospitals providing homeopathic treatment within the NHS. Homeopathic hospitals were incorporated into the NHS at the time of its establishment. Many NHS pain clinics offer acupuncture. Some CAM therapies such as aromatherapy and massage are provided to inpatients as part of integrated cancer care or palliative care in NHS hospitals (Lewith, 2000; National Institute for Clinical Excellence, 2004).

Primary care provision of CAM therapies is provided in-house by sessional complementary therapists, by general practitioners (GPs) or other members of the primary health care team, on referral to a local independent complementary therapy clinic, or by complementary therapists in an adjacent complementary health centre (Luff and Thomas, 2000). One in two primary care practices in England offered some access to CAM in 2001, compared to 40 percent of practices in 1995 (see Figure 2.1). More practices were providing CAM therapies in-house, with no increase in the proportion of practices making referrals. The proportion of practices with an independent CAM practitioner working in the practice doubled between 1995 and 2001 (6.1% to 12.2%). It was more common for practices to provide acupuncture and homeopathy through members of the primary health care team and manipulative therapies, e.g. osteopathy or chiropractic, through independent practitioners (Thomas, Coleman et al., 2003).

Funding for these services may be from local NHS budgets, from a registered charity or charitable trust, or paid on a fee-for-service basis by patients out of pocket. In 2001 the proportion of services provided through primary care practices in England for which the patient had to make a partial or full payment rose to 42 percent from 26 percent in 1995 (Thomas, Coleman et al., 2003).

Public funding of CAM is largely dependent on the decisions of those responsible for local NHS budgets. Between 1991 and 1997 GP fundholders and health authorities made these decisions. Since 1997 purchasing has been the responsibility of primary care groups or primary care trusts (referred to here as primary care organisations).

Figure 2.1 Percentage of GP practices offering access to CAM services by therapy type in 1995 and 2001



Source: (Thomas, Coleman et al., 2003)

In 1994, a survey of health authority public health directors (n=171 response rate 57%) found 67 percent of health authorities purchased one or more CAM treatments. The most common were homeopathy and acupuncture followed by osteopathy, aromatherapy and chiropractic. Only ten health authorities had an established policy on complementary therapies, with a further ten in the process of developing a policy (Adams, 1995).

In a survey of primary care organisations in 2000 (60% response rate) 58 percent reported that they provided access to CAM via primary care (Bonnet, 2000). The most commonly provided therapies were acupuncture (73%), osteopathy (43%), homeopathy (38%), chiropractic (23%) and aromatherapy (18%). This is similar to findings of an earlier study of health authorities (Adams, 1995). A survey of primary care organisations in 2003/4 in England estimated that 43 percent were providing access to three or more CAM therapies (Wilkinson, Peters et al., 2004). The most common therapies to which access was provided were acupuncture, osteopathy, homeopathy, massage, aromatherapy, and reflexology.

2.3.2 Private financing

The majority of CAM services in the UK are paid for privately (out of pocket). In a Scottish survey only 21 percent of respondents had received treatment free of charge (Emslie, Campbell et al., 1996). A 1998 survey found that 79 percent of CAM visits in England were paid directly by the patient, with a mean annual expenditure of £108 per paying user (Thomas, Nicholl et al., 2001). The self-reported amounts spent on CAM by

patients vary enormously. In a 1999 BBC poll CAM users were found to be spending on average £13.62 per month on treatment, but 37 percent were spending less than £5 per month (Ernst and White, 2000). Half of asthma patients spent less than £50 on CAM in the preceding year, while eight percent spent over £100 (Ernst, 1998a). Among women diagnosed with breast cancer the mean average CAM consultation cost was calculated as £10.66 (Rees, Feigel et al., 2000). The majority of consultations for children cost less than £20 per visit (Simpson and Roman, 2001).

In 1998 total out-of-pocket expenditure on six established therapies (acupuncture, chiropractic, homeopathy, hypnotherapy, herbalism and osteopathy) was estimated at £450 million in England (Thomas, Nicholl et al., 2001). Industry reports estimate that spending on CAM (including over-the-counter products) was £640 million in 2000, with practitioner visits accounting for about three-quarters of market value (Market Assessment International, 2000).

There is no published data on how much private health insurance companies spend reimbursing the costs of CAM therapies. Private health insurance products that cover CAM therapies are widely available, and at least one insurer has established links with a provider of CAM therapies (Foubister, Thomson et al., 2005). Data from population surveys is now old. In 1988 fewer than one in five of non-NHS CAM consultations were covered by private health insurance (Yung, Lewis et al., 1988). In 1986 90 percent of adults in Cardiff who had used CAM reported that no contribution was made to the costs by private health insurance (Yung, Lewis et al., 1988). Among a sample of women with breast cancer who reported using CAM in 1997, nine percent had their CAM consultation funded by the NHS, 14 percent were covered by health insurance, while three-quarters had to pay out-of-pocket (Rees, Feigel et al., 2000).

2.3.3 Discussion

There is some access to CAM directly within the NHS, mostly provided by doctors and other statutorily regulated practitioners. Few CAM practitioners are directly employed within the NHS. Although there has been a small increase in the number of osteopaths and chiropractors located within primary care since they were statutorily regulated, they continue to work as independent practitioners. It is not clear whether regulation is a barrier to increased integration.

Neither is it clear to what extent NHS funding of CAM services will increase in future, despite the arguments put forward to support this (Smallwood, 2005). Access will depend on purchasing decisions taken at a local level, as well as recommendations at national level

by the National Institute for Health and Clinical Excellence (NICE). Differences in purchasing policies between NHS purchasers depend on organisational priorities and the level of autonomy over budget allocations. The current lack of regulation of CAM practitioners may also be a barrier to greater NHS funding of CAM (NHS Confederation, 2000).

Most CAM practitioners work in the private sector where only minimal trading standards apply. Consumers must assess qualifications and prices in this market where *caveat emptor* applies. As practitioners are free to set their own prices the prices faced by consumers are highly variable. Furthermore, most consumers cannot rely on a referral from a GP but chose a practitioner on the basis of a recommendation from a friend or relative. Consumers currently lack access to reliable information on training/qualifications on which to base an informed choice. Regulation could help address these information asymmetries.

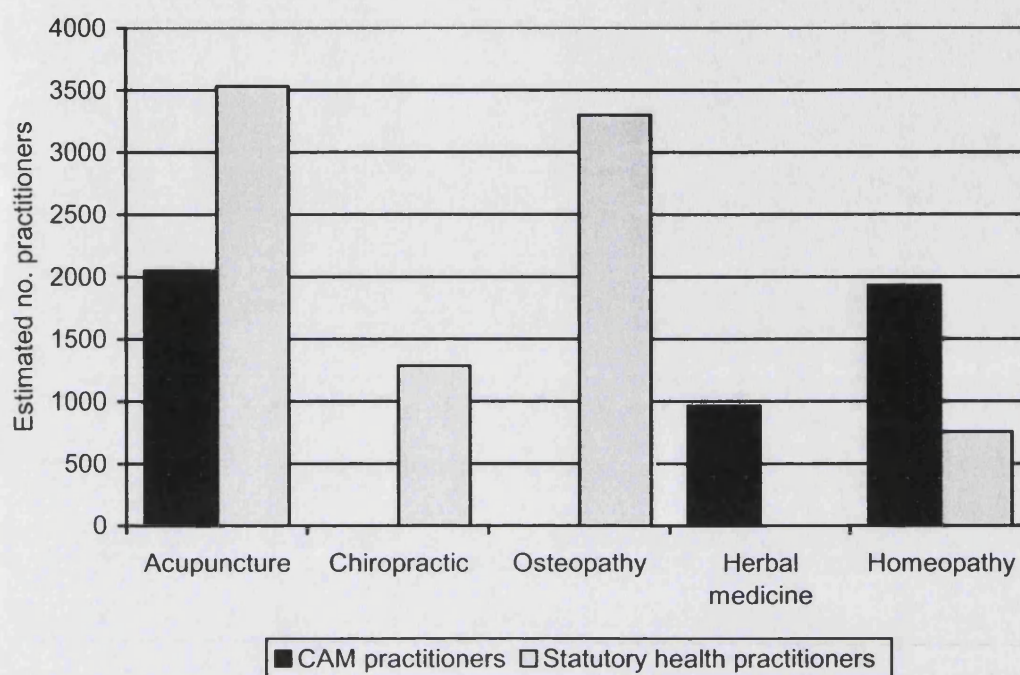
Data on costs is limited and lacks the detail necessary for use in cost-effectiveness studies. Any future attempts to undertake cost-effectiveness studies in the area of CAM will require more accurate ways of measuring the costs (as well as the benefits) of treatments than self reported surveys of aggregate out-of-pocket spending (Hulme and Long, 2005). Future studies could usefully collect data on price-per-consultation, consultations-per-episode of care, quantity and price of recommended products or remedies purchased from the practitioner or over-the-counter.

2.4 Who provides CAM services?

The majority of CAM treatments are provided by complementary therapists, with other health professionals accounting for 20 percent of treatments (Emslie, Campbell et al., 1996). There has not been a systematic data collection of the number of people practising CAM in the UK since 1999. In the UK anyone is free to practise whether they are a statutorily regulated health professional or not.

Figure 2.2 gives an overview of the estimated numbers of practitioners in 1999 for each of the five therapies to be examined in this study. The majority of those who practise acupuncture are statutorily regulated professionals or medical acupuncturists whereas among those practising homeopathy the majority are non-medical or lay homeopaths. The study did not identify any statutorily regulated professionals practising herbal medicine. There are also people who practise CAM on either a paid or a voluntary basis with or without training but who are not registered with either a statutory or a voluntary professional body. It is, therefore, almost impossible to obtain data on the number of these practitioners.

Figure 2.2 Estimated number of practitioners for selected therapies in 1999



Source: (Mills and Budd, 2000)

2.4.1 Statutorily registered health care professionals

Some health care practitioners such as doctors, nurses, midwives and physiotherapists provide CAM therapies as part of their care for patients both in the NHS and outside it, for example in hospices and the private sector. A report for the Department of Health estimated that there were 9,300 statutorily registered health professionals practicing some form of CAM. The report acknowledged that due to the paucity of data it was possible that there were up to 20,000 practising (Mills and Budd, 2000).

There are a number of dedicated associations for statutorily registered health care professionals practising CAM therapies such as the British Medical Acupuncture Society (BMAS), the Faculty of Homeopathy, the Acupuncture Association of Chartered Physiotherapists (AACP) and the British Academy of Western Acupuncture (BAWA).

The BMAS currently has 2,500 members including doctors, nurses, midwives, health visitors, physiotherapists, osteopaths, chiropractors and podiatrists. It provides training at foundation level to approximately 450-500 trainees per year. In 2002 a BMAS audit found that between 50 and 60 percent of those who had done the training were using acupuncture techniques six months later. A smaller proportion went on to do further training towards accreditation (Cummings, 2005). In 1999 the BAWA which mostly represents nurses reported 250 members. In 1999 the AACP had 1,600 members by 2003 it

was reported to have 2,650 members (Acupuncture Regulatory Working Group, 2003). There was over 50 percent growth in the number of statutory health professionals registered with one of these three organisations between 1997 and 1999 (Mills and Budd, 2000).

The Faculty of Homeopathy has an international membership of over 1,400 (Faculty of Homeopathy, 2005). Membership is open to all statutorily registered professionals. The Faculty provides training courses for a range of practitioners including doctors, veterinary surgeons, dentists, pharmacists and nurses.

There are 60 doctors who hold dual registration with the General Medical Council (GMC) and the General Osteopathic Council (GOsC) (Clarke, 2005). The British Osteopathic Association (BOA) continues to represent the interests of doctors practising osteopathy. The General Chiropractic Council (GCC) currently has only 2 members who hold dual registration with the GMC (General Chiropractic Council, 2005d).

There is active interest in CAM among nurses and significant numbers with training. In 2000 the Royal College of Nursing Complementary Therapy Forum had as many as 10,000 members (Mills and Budd, 2000). An in-depth study by the NHS Confederation into CAM provision in one health authority in 1996 found that 34 percent of midwives and 18 percent of nurses were providing CAM services (Trevelyan, 1998). In a survey of staff providing cancer care in Southampton (the majority of whom were nurses), 21 percent reported having training in some form of CAM (Lewith, Broomfield et al., 2002). Yet the practice of CAM therapies by nurses and midwives in hospital settings is currently unrecorded and unmonitored.

2.4.2 Registered CAM practitioners

Two surveys were conducted in 1997 and 1999 by academics at Exeter University commissioned by the Department of Health. These provide the only comprehensive estimates of the number of (voluntarily) registered CAM practitioners in the UK. In 1999 there were an estimated 49,000 CAM practitioners, up from 40,000 in 1997, though it was thought that the true number might exceed 60,000 (Mills and Budd, 2000). The numbers of practitioners of acupuncture, chiropractic, homeopathy and osteopathy grew steadily between 1997 and 1999 (up nearly 40%). The numbers of less well-established therapies such as Ayurveda more than doubled.

In osteopathy and chiropractic registration is now mandatory. The GCC had 1,950 registrants and the GOsC 3,451 registrants at 20 January 2004 (Department of Health, 2004a). This compares to the 203,398 registrants of the GMC (Allsop, Jones et al., 2004).

Before statutory regulation, the King's Fund Working Party on Osteopathy identified eight registering bodies with an estimated membership of 2,000 osteopaths, of whom about 200 were members of more than one organisation (King's Fund, 1991). The chiropractic profession had less than 1,000 members, most of whom were covered by one of three voluntary registers (King's Fund, 1993).

In acupuncture, herbal medicine and homeopathy where registration is voluntary estimates are more difficult. Many practitioners who practise multiple therapies may be listed on more than one register and several associations have more formal overlap of membership.

The Department of Health estimated that a joint council for herbalists and acupuncturists would have a total of 3,700 registrants. The British Acupuncture Council (BAcC) currently has over 2,500 registered acupuncturists (British Acupuncture Council, 2005). The Herbal Medicine Working Group based its cost estimates for a Herbal Council on the basis that 1,300 herbal practitioners would register (Herbal Medicine Regulatory Working Group, 2003, para 598). This may be a conservative estimate given that there are between 1,000 and 3,000 traditional Chinese medical practitioners, some of whom are members of small associations such as the Association of Traditional Chinese Medicine (about 400 members) (O'Farrell, 2004).

There has been growth in the number of non-medical homeopaths. The number of registrants with the Society of Homeopaths grew from 41 shortly after its establishment in 1981 to 165 in 1990, 708 in 1999 and 1476 in 2004 (Morrell, 1999; Council of Organisations Registering Homeopaths, 2003). Although the Society is the largest of the registering bodies the Council for Organisations Registering Homeopaths (CORH) has nine other member organisations that register homeopaths. The Homeopathic Medical Association (250) and the Alliance of Registered Homeopaths (249) are the other largest registering bodies. The Association of Natural Medicine, the British Register of Complementary Practitioners, the International Register of Consultant Herbalists and Homeopaths, the International Guild of Professional Practitioners, and the Fellowship of Homeopaths have less than 50 homeopathic members each (Council of Organisations Registering Homeopaths, 2003). Besides the numbers of registered practitioners there are other indicators of growth.

An analysis of entries in the Yellow pages between 1992 and 2002 showed that seven out of the ten classifications with the largest increase in entries were in professions catering for beauty and body image, alternative therapy and stress relief (Yell, 2004). Entries by aromatherapists grew by 5200 percent (the single largest classification change in the entire census, having first appeared in 1993), reflexology by 829 percent and the Alexander

Technique by 724 percent. Chiropractors entries rose by 157 percent, herbalists by 123 percent and acupuncture practitioners by 83 percent. These data do not necessarily represent actual growth in practitioner numbers but are indicative of commercialisation of CAM practice.

Data on university-based courses also indicate growth in practitioner numbers. The number of students accepted to study complementary therapies³ grew by around nine percent per annum between 2002 and 2004 and by as much as 21 percent between 2004 and 2005 (UCAS, 2006). However, the ratio of applications to acceptances fell over this period with only 2.4 applications for each place in 2005. These courses are easier to get on than other subjects allied to medicine. Table 2.1 shows the number of CAM-related courses offered by higher education colleges and universities in the UK in 2005. The majority of courses lead to a Bachelor's degree in science (BSc). Better data is needed on the number, length, and content of courses currently offered in further and higher education and through private course providers in order to develop appropriate regulation and course accreditation.

Table 2.1 **Number of courses available in UK higher education colleges and universities for five CAM therapies, 2007**

<i>Subject</i>	<i>Number of courses available (details)</i>
Acupuncture	9 (3-4 years full-time Hon BSc) often part of traditional Chinese medicine training
Chiropractic	3 (5 year full-time Hon M Chiro, 4 year full-time Hon BSc, 1 year full-time foundation year)
Herbal medicine	8 (3-4 years full-time Hon BSc with or without foundation)
Homeopathy	3 (3-4 years full-time Hon BSc with or without foundation)
Osteopathy	6 (4 year full-time Hon BSc, 5 year full-time Hon BOstMed, 4 year full-time Degree BOst)

Source: Author's compilation using data from (UCAS, 2006)

There is anecdotal evidence that mono-therapeutic practice is in ascendance and multi-therapeutic practice in decline. The increasing demands of university courses and registration requirements mean that more practitioners specialise in a single therapy and work full time. There is also a perception that fewer practitioners work from home and instead work in commercial group practices. More than 20 years ago almost half of registered CAM practitioners whose primary practice was in one of six therapies (acupuncture, chiropractic, homeopathy, medical herbalism, naturopathy and osteopathy) practised a second therapy and a quarter practised a third therapy (Davies, 1984). In 1984 the highest levels of full-time practice were among chiropractors and osteopaths (88% and

³ Based on the UCAS classification system (JACS) subject code for complementary medicine (B3) which includes osteopathy, chiropractic, chiropody, Chinese medicine, herbalism, acupuncture, aromatherapy, hypnotherapy and reflexology.

86% respectively) and the lowest levels among acupuncturists and homeopaths (Davies, 1984). It is likely that CAM therapies with less developed professional structures have higher levels of part-time working.

2.4.3 Discussion

A large and increasing number of statutorily regulated health care professionals who work in the NHS practise CAM. There is currently no systematic record kept of training or practice of CAM therapies by staff working within the NHS. The Kerr/Haslam Inquiry into cases of sexual abuse by psychiatrists actually recommended that:

procedures and policies should be put in place ...to ensure that all NHS organisations are aware of the therapies being undertaken by all staff...[and specifically that] no member of the health care team should be permitted to use or pursue new or unorthodox treatments without discussion and approval by the team (such approval to be recorded in writing) (Department of Health, 2005c, p293).

It is not clear that NHS providers have put in place such policies. NHS providers that employ staff who practise CAM therapies on patients should consider the implications for clinical governance.

Existing data is limited to the number of CAM practitioners. A more comprehensive census is needed which would collate data on the demographics (e.g. age and gender of the workforce), working terms and conditions (e.g. part-time, full-time, self-employed), setting (e.g. solo or group practice, co-located with conventional medical practice, community or inpatient), therapeutic range (e.g. mono-therapeutic vs. multi-therapeutic), geographical location and income of CAM practitioners. Data of this sort would enhance understanding of the changing patterns of practice and the nature of the workforce. Without such information it will be difficult to design regulation or estimate the costs and impacts of different options.

2.5 Discussion

The widespread use of CAM by the population, and especially by people with diagnosed medical conditions, makes it all the more surprising that practitioners are largely unregulated. There are increasing numbers of CAM practitioners and growth is likely to continue given the expansion in higher education courses in complementary therapies. Commercial private schools and course providers will continue to offer more flexible training options where there is demand for these. These trends present a challenge for those who wish to see standards of training monitored and course providers accredited.

Availability of CAM in primary care is increasing, and large numbers of statutorily regulated professionals are practising CAM within the NHS. The increased integration of CAM raises questions about the lack of regulation to which CAM practitioners are subjected, and the absence of standards of training for doctors, nurses, midwives and dentists practising CAM. The lack of regulation might also put some NHS providers in breach of their clinical governance requirements.

The majority of treatments are paid for out of pocket by users to independent practitioners. In some areas NHS purchasers have used their local flexibilities to provide access to integrated services or to fund referral to CAM practitioners. There remain large variations in access to CAM across the UK and between socio-economic groups. The lack of regulation means that many local NHS purchasers are reluctant to formalise availability of CAM services. Consumers and local purchasers must assure themselves of the quality and training of those they seek care from or contract with.

Given the size of the market in CAM services described here it is perhaps no surprising that the issue of regulation is firmly on the policy agenda. Patient demand is likely to grow in future and practitioner numbers to expand. In the next chapter we explore some of the regulatory options and how these might apply to the regulation of CAM practitioners. The chapter uses examples from other countries to illustrate some of the different approaches to the regulation of CAM.

3 MODELS OF REGULATION

3.1 Introduction

The growth in the market for CAM services is not unique to the United Kingdom. The World Health Organization (WHO) estimated the global value of the trade in herbal medicines and other traditional and complementary medicinal products at over US\$ 60 billion in 2003 (Bodeker, Ong et al., 2005). The indications are that use of practitioners is also widespread in other developed countries (Institut für Demoskopie Allensbach, 2002; Eisenberg, 2003; Andrews and Boon, 2005). WHO has called on governments to implement national policies on traditional medicine and complementary medicine (World Health Organization, 2002, p5). Specifically, it has suggested that legislation and regulation for herbal products and practice of therapies be introduced, together with policies on the education, training and licensing of providers. While some countries have had legislation in place for many years (e.g. Germany) others have only established the legal basis for the practice of CAM more recently (e.g. Norway). The approach taken in different countries varies.

There are a range of regulatory options available to policymakers. A number of authors have examined their application to health care in general (Saltman, Busse et al., 2002; Walshe, 2003) but not to the regulation of CAM practitioners. The main body of this chapter examines the range of strategies that could be adopted for the regulation of CAM practitioners. These are illustrated with examples of how regulation is applied in a number of countries.

The chapter begins with an overview of recent international developments in the regulation of CAM practitioners.⁴ It discusses the regulation of CAM practice in Germany and Norway in more detail. Section 3.3 presents a framework of regulatory strategies. Each regulatory strategy identified in the framework is then examined in more detail in sections 3.4 – 3.10 using examples from the UK and other countries to illustrate. We will return to these strategies in the concluding chapter where I discuss the regulatory options for policymakers in the UK.

⁴ Although there have been interesting developments in the regulation of CAM products internationally particularly herbal medicines, the focus here is on practitioners.

3.2 International experience

Recent regulatory activity in a number of countries has generated information on and policy discussion about how other countries regulate CAM practitioners. In the mid-1990s the Australian government commissioned a review of occupational regulation of CAM in a number of other countries (Bensoussan and Myers, 1996). In 2002 the Irish government commissioned a report which included an analysis of the regulation of CAM practitioners in a number of countries (O'Sullivan, 2002). The most extensive published assessment of regulatory alternatives by policymakers in relation to CAM was conducted in Norway, prior to changes in the law which were introduced in 2003 (see below). There have also been two reports commissioned by the European Union (EU) on the legal aspects of CAM (Monckton, 1998; Erdsal and CAM-CANCER Consortium, 2005).

In contrast to the UK where CAM practise has been 'tolerated' under common law, in countries with civil or Napoleonic law, unless explicitly permitted, the practice of medicine has been illegal by anyone other than licensed medical practitioners. Legislative changes have been introduced in Netherlands (1998), Belgium (1999), Portugal (2003), and Denmark (2004). These have put CAM practitioners on a different legal footing. Germany has had a regulatory framework in place for many years for CAM practitioners as well as standards of education and training for conventional medical practitioners who practise CAM. These arrangements are discussed in more detail below together with Norway which has introduced legislation more recently.

3.2.1 Germany

In Germany use of CAM is widespread and somewhat more integrated with conventional medicine than in other European countries. Non-medical CAM practitioners (*Heilpraktiker*)⁵ are regulated by the state on the basis of the *Heilpraktikergesetz*, which was introduced in 1939 and modified in 1974, 1997 and 2000. There are very few formal requirements for *Heilpraktiker*. In order to qualify for a licence the applicant must have completed primary education, have German or EU citizenship, must be at least 25 years of age, and must provide a clearance certificate and a medical certificate confirming that there is no indication of a physical or mental health problem or of drug abuse which would limit the applicant's suitability to perform CAM.

No formal proof of qualification is needed, but applicants are required to pass an examination at a local public health office (which operates under the supervision of the

⁵ The six leading *Heilpraktiker* associations have a combined membership of over 20,000, representing about 90% of all *Heilpraktiker* (Fachverband Deutscher Heilpraktiker, 2006).

respective federal state). Applicants must prove that they have sufficient knowledge and abilities to practise as *Heilpraktiker*, but this mainly means that they have to show that their treatment does not negatively affect public health and that they know the legal limits to their practice (World Health Organization, 2001). Candidates are tested on basic clinical knowledge and skills, biomedical understanding of the body, and on legal regulation of their profession.

The law (*Heilpraktikergesetz*) specifies that applicants who wish to specialize in one form of CAM or *Heilpraktiker* who want to specialize after having obtained a licence should be tested on their knowledge of that specific therapy. However, there are few standards or rules which specify what knowledge is required. According to WHO estimates (2001) about ten percent of *Heilpraktiker* have never received any formal training in CAM.

In addition to CAM treatment, *Heilpraktiker* can offer a variety of basic medical services such as blood sugar tests and electrocardiograms. However, they are legally prohibited to prescribe prescription-only medicines, give or provide anaesthetics or narcotics, practice obstetrics or gynaecology, treat venereal diseases and diseases which require notification, issue death certificates, perform autopsies, or X-ray. The rationale behind this is to protect patients against fraud, malpractice and misleading information.

Since 2003, it is compulsory for medical faculties to include training in naturopathy and physical therapy in the curriculum (Dobos and Michaelsen, 2002). However, the compulsory training units are short (14 hours of seminars and 28 hours of lectures over two semesters). Doctors can also acquire specialist qualifications (*Zusatzbezeichnungen*) in acupuncture, allergology, naturopathy, physical therapy, balneology and special pain therapy. Training requirements are regulated in the Code of Training produced by the regional medical associations based on guidelines provided by the Federal Medical Association (*Muster-Weiterbildungsverordnung*). There is always a mandatory period of practice and an official curriculum of procedures and skills to be learnt (Dixon, Riesberg et al., 2003). In naturopathy for example, doctors are required to undertake either six months training in a hospital specialized in CAM, or to work three months in a practice under the supervision of an office-based doctor with CAM specialization and participate in an additional 160 hours of seminars (Bundesärztekammer, 2005).

Doctors are only allowed to use a CAM title (e.g. acupuncturist, homeopathic doctor) if they hold the respective qualification. However, there are no legal restrictions on doctors offering any form of CAM without qualification. Doctors are liable for their actions and may be sued for malpractice by the patient. In cases of severe malpractice the Medical

Chamber (*Årzttekammer*), the self-regulatory body for doctors, may take legal action against a doctor.

3.2.2 Norway

The report prepared by the Norwegian government on the regulation of alternative medicine distinguished between negative regulation and positive regulation. Strategies considered under negative regulation included the application of criminal law or compensation law, the withdrawal of licence/authorisation to practise, registration privilege, and supervision of professional activities. Examples of positive regulations given were those that recognise and encourage certain activities, such as the right to register, opportunity to be accredited, right to reimbursement for patients, practitioners and businesses, and right to treatment. Finally, they identified what they termed ‘non legal measures’ which included educational measures (e.g. information bank, research and development programme), organisational measures (e.g. collaboration projects), and economic measures (e.g. financial support for production of information, for local government and county councils, for research and co-operative projects between alternative and conventional medicine) (Alternative Medicine Committee, 1998).

In 2003 the Norwegian government introduced new legislation to regulate CAM practitioners and abolished the prohibition of ‘quackery’. The Act No. 64 of 27 June 2003 relating to the alternative treatment of disease, illness etc., and regulations specifying its implementation, came into force in 2004. They provide a legal mechanism for registering voluntary self-regulatory bodies and their members. Previously under the Medical Quackery Act of 1936, the practice of medicine by anyone other than registered practitioners⁶ was illegal.

To qualify for registration, a practitioner must be a member of a professional organisation that is ‘approved’ by the Norwegian Directorate for Health and Social Affairs. In order to receive approval, associations must have education and training requirements, a code of ethics, and standards of practice. Provisions must also be in place regarding a practitioner’s duty to provide information to patients, protection of data, a patient’s right to complain, and sanctions against members. Associations are required to have at least 30 members and must be registered in the Central Coordinating Register for Legal Entities.

CAM practitioners do not need a licence to practise but practitioners are encouraged to register on a voluntary basis with the newly established Brønnøysund Register Center. Only those CAM practitioners who are registered may use the title ‘registered’. Applicants must

⁶ Since 1988 chiropractors are considered licensed health care personnel and are regulated under the Health Personnel Act.

be either self-employed, employed by a registered employer, or a partner in a registered general partnership (registration refers to the status as a legal entity). They must also be insured for any financial liability to patients. In order to maintain registration members must submit documentary proof that they meet these requirements and pay an annual fee set by the Ministry of Health.

Sections 5-7 of the Act specify that CAM may only be practiced if the purpose of the treatment is to alleviate or moderate symptoms, the patient is old enough to give his consent to alternative treatment under the Patients' Right Act, the treatment is authorized by a medical doctor, or if no other treatment is available. Under existing legislation CAM practitioners are not allowed to use controlled medications in treatment, surgery, injections, anaesthesia, and other methods of diagnosis and treatment restricted to physicians. Serious health hazards and diseases defined in the Communicable Disease Act are only to be treated by specific health personnel, such as doctors and nurses.

The new Act also requires that marketing of CAM be carried out in an objective and factual way and in a manner which helps to safeguard the patient's safety. The therapist's name, address, telephone number and other necessary contact information must be clear in any marketing.

These two examples illustrate that there are different ways in which the state can act to influence the actions and practice of CAM practitioners and conventional medical practitioners who practise CAM. The remainder of this chapter analyses a series of regulatory options and considers how they might apply to the regulation of CAM practice. Examples of regulations from the UK and elsewhere are used as illustrations.

3.3 Regulatory strategies

Regulation has been variously defined. Selznick (1985) defines regulation as "sustained and focused control exercised by a public agency over activities which are valued by a community" suggesting it is more than legislation (Selznick, 1985). Baldwin and Cave (1999) identify three ways regulation can be understood:

- i) as a specific set of commands;
- ii) as deliberate state influence
- iii) as all forms of social control or influence (Baldwin and Cave, 1999).

The definition of regulation used here is close to (ii) above, that is actions taken by the state intended to influence the behaviour of independent actors (in this case CAM practitioners). Regulation may seek to influence who is able to practise (licensing), the titles they use, how they advertise and market their services (false claims), the quality of education and training (accreditation), the quality of the services they provide (trading standards), how they interact with patients (codes of ethics and practice), the price they charge, and the information they provide to consumers (disclosure).

In order to examine the range of regulatory options and how they apply to CAM practitioners I use the following classification: command and control, self-regulation, incentives, market harnessing, disclosure, direct action, rights and liabilities, and public compensation (Baldwin and Cave, 1999). Table 3.2 provides an overview of the regulatory strategies with examples for illustrative purposes. As was discussed above other countries have adopted different regulatory strategies. These examples, together with those from the UK, are used to illustrate the eight different approaches to regulation set out in Table 3.2.

Table 3.2 **Regulatory strategies and their application to the regulation of CAM practitioners**

Strategy	Example
Command and control (legislative rules)	Anyone who has not completed a medical degree is prohibited from practising medicine including CAM. All CAM practitioners are required to have personal liability insurance by law or face penalties/sanctions.
Self-regulation	CAM practitioners establish a professional body which defines and enforces standards of practice.
Incentives	Professional fees and tuition costs for accredited courses paid by CAM practitioners are tax deductible.
Market harnessing controls	Public purchasers specify standards in contracts with CAM practitioners.
Disclosure	All CAM practitioners required to display valid certificate of insurance.
Direct action	CAM training courses are state sponsored
Rights and liabilities laws	The patient has a right to a duty of care. Consumers can sue a CAM practitioner for negligence.
Public compensation	No fault liability scheme for anyone harmed by treatment given by registered CAM practitioners.

3.4 Command and control

Command and control regulation can be understood as “The exercise of influence by imposing standards backed by criminal sanctions” (Baldwin and Cave, 1999, p35). Regulation in this context may be enabling (i.e. demand certain positive action to be taken)

or prohibitive (i.e. make certain activities illegal). In relation to professionals legislation may be used to protect designated titles, limit the use of reserved procedures, require registration or to provide legal backing to disciplinary codes.

In several European countries the practice of CAM by non-medically qualified practitioners is illegal. These systems have been classified as monopolistic (Monckton, 1998; Bodeker and Kronenberg, 2002) or exclusive (World Health Organization, 2002). Recently, prohibitive regulation has been replaced in a number of these countries by a more permissive regulatory environment. For example, the practice of CAM was decriminalized in the Netherlands in 1998 following the Health Care Profession Bill 1993. In 1999 the Government of Belgium adopted a law recognizing homeopathy, chiropractic, osteopathy and acupuncture, and which allows for the addition of other CAM therapies in future. In 2003 Norway passed legislation to permit the practice of medicine by registered CAM practitioners, though with some limits. The Portuguese parliament passed legislation in July 2003 to regulate the practice of acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractic, which had previously been illegal for non-medical professionals (Erdsal and CAM-CANCER Consortium, 2005). Prohibition of the practice of medicine other than by registered health professionals remains in force in Austria, France, Italy and Spain, although in most countries CAM practitioners operate without prosecution (Erdsal and CAM-CANCER Consortium, 2005).

The Medical Act 1858 and its subsequent revisions did not prohibit the practice of medicine in the UK but only the use of the title 'registered medical practitioner'. However, a number of general laws in force in the UK have implications for the practice of CAM. The following were highlighted by the Department of Health in their submission to the House of Lords' Select Committee (Department of Health, 2000b):

- The Health and Safety at Work Act 1974: duty to ensure the health and safety of people affected by activities undertaken on premises;
- The Food Safety Act 1990: controls the sale and supply of non-medical products for human consumption;⁷
- Trade Descriptions Act 1968 and Consumer Protection Act 1987: apply to professions making claims for the goods or services they sell;
- Charities and Companies Acts (if they are registered as charities or limited companies or both);

⁷ The implementation of the EU Directive on Traditional medicinal products into UK law means that some products previously regulated under the Food Safety Act are now considered medicines.

- London Local Authorities Act 1991 requires the licensing of premises used for activities which include acupuncture, massage, and other special treatments;
- Cancer Act 1939 and other similar legislation: prohibit non-medically qualified individuals from prescribing controlled drugs, claiming to cure or in some cases treat specific illnesses and medical conditions (e.g. cancer, diabetes, epilepsy, glaucoma, tuberculosis and venereal diseases), and from performing specific medical acts such as abortion.

In addition, the Osteopaths Act 1993 and the Chiropractors Act 1994 created the General Osteopathic Council (GOsC) and the General Chiropractic Council (GCC) respectively. Legislation requires that they maintain a register, gives legal backing to disciplinary procedures and provides protection of titles.

3.4.1 Protection of title

Legislation can be used to restrict the use of designated or protected titles to certain professionals who meet defined statutory requirements. Also called ‘certification’, it has been defined as when:

some authority or agency is empowered by statute to certify individuals to the public as having satisfied particular educational and training requirements judged...to indicate competence in a particular range of professional services...[it] typically involves exclusive legal appropriation of a generic occupational description, usually in conjunction with such a term as ‘registered’ or ‘certified’ (Wolfson, Trebilcock et al., 1980, p203).

Anyone using the reserved or protected title who does not meet the specified requirements can be prosecuted. Protection of title overcomes problems of information asymmetry, where patients have less information than the provider does about the quality of the service or at least the qualifications of the provider. Consumers can be confident that a practitioner using the protected title meets the required standards of training. In contrast to licensing (see 3.4.3 below) it allows free entry to the market for uncertified practitioners. This may have advantages in ensuring a competitive market but if the costs of error are high, as they are in health care, certification may not provide a sufficient guarantee of quality (Wolfson, Trebilcock et al., 1980). There are a number of examples of the use of protected titles in relation to CAM practitioners. Both ‘osteopath’ and ‘chiropractor’ are protected in the UK, the title of ‘Chinese medicine practitioner’ is restricted in Hong Kong, and only doctors

who have taken formal qualifications may use the title of 'acupuncture doctor' or 'homeopathic doctor' in Germany.

Titles are often reserved for use by 'registered' or 'certified' practitioners. In Norway, it is the association rather than the individuals that are registered in law (see 3.2.2 above). Individual members of the 'approved' associations may then apply for registration (on a voluntary basis) in order to call themselves a 'certified' practitioner. A similar model was implemented in Denmark in June 2004 and is being introduced in Ireland following the recommendations of the National Working Group on the Regulation of Complementary Therapists (Erdsal and CAM-CANCER Consortium, 2005; Department of Health and Children, 2006).

3.4.2 *Reserved procedures*

The concept of reserved procedures refers to procedures that may only be performed by categories of professionals authorised to do so by law. The performance of these acts without authorisation is a criminal offence. This is often referred to as regulation of the scope of practice, or protection of function. In most countries there are reserved procedures for doctors or other registered health professionals. These commonly include prescription and administration of drugs, death certification and other official administrative duties, surgical and obstetric procedures (including abortion), treatment of venereal or communicable diseases, administration of anaesthetics, X rays, and other diagnostic procedures.

There are a few examples of where CAM practitioners have reserved procedures. In Denmark CAM providers are not permitted to use needles except under the supervision of an allopathic physician (Erdsal and CAM-CANCER Consortium, 2005). In the UK the use of powerful herbal medicines (as defined under SI 1977/2130) was restricted to 'herbal practitioners', though this term was not defined, making the law difficult to enforce (McIntyre, 2001). These rules have been amended by subsequent legislation which implements the EU Directive on traditional herbal medicinal products (2004/24/EC) into UK law (SI 2005/2750; SI 2005/2745; SI 2006/395). Under Section 12(1) of the Medicines Act 1968 herbalists are also permitted to make up unlicensed herbal remedies to meet the needs of individual patients following a consultation. Again, because herbalists are not defined in law it has not been possible to enforce this as a reserved procedure.

3.4.3 *Licensure*

Market entry of providers can be controlled through the issuing of licences that require certain standards to be met. Licences can be rescinded after a certain period or if a complaint against the provider is upheld. The law may require someone to hold a licence in order to undertake a particular activity (such as a driving licence) or consume a particular good or service (such as a TV licence). Licensure is used in relation to the supply of goods or services to limit the number of entrants in to a particular market. Licences may be issued for a product, a provider or the premises where the provider operates.

Legislation may require that the names of all those individuals wishing to provide a particular service are entered in a register. Entry to the profession can thus be controlled, in essence de-barring non-registered practitioners. By giving registered practitioners an exclusive right to practise, this in effect creates a system of licensure.

Because of the legal situation in the UK, CAM practitioners may freely practise medicine without a licence under common law. Practitioners are required to register in order to use protected titles (see above). In other countries, CAM practitioners are required to obtain a licence in order to practise by either passing a licensing exam or holding a recognised qualification. For example the Ministry of Health, Labour and Welfare in Japan issues licences to CAM practitioners who pass a national examination after graduating from an accredited school or training institution. In China practitioners have to pass a licensing exam designed by the Health Department and administered in the provinces. On successful completion of the exam the local health department issues a certificate which specifies any limits to the scope of practice, and permits the practitioner to practise within that area. In Germany, as we have seen, to be licensed as a *Heilpraktiker* practitioners must pass an exam at one of the public health offices which operate under the supervision of the states (*Länder*).

Some registering bodies require re-licensing or re-certification by providing proof of participation in continuing medical education. Chiropractors in Alberta, Canada, have to provide proof of participation in continuing education every three years in order to maintain their licence to practise.

In England, many local authorities have enacted bylaws which require the premises in which acupuncturists practise be licensed, usually under the same regulations which require tattooists to be licensed. The British Acupuncture Council (BAcC) publishes a Code of Safe Practice which some local authorities use as the basis of their standards (British Acupuncture Council, 2004a).

3.4.4 *Disciplinary procedures*

In many countries the responsibility for setting standards, monitoring compliance and disciplining practitioners is delegated to a self-regulating body (see 3.5 below).

The disciplinary procedures may, however, have legal backing and be linked to certification or licensing. Often disciplinary procedures for sanctioning practitioners who fail to meet standards are only exercised in extreme cases of professional misconduct or in response to an allegation of misconduct. The sanctions available range from warnings, suspension or removal from a register or removal of licence. If a violation is serious the matter may be referred to the police and enforced through the courts using fines or even imprisonment. Standards may be monitored using information from consumer complaints, inspection, peer review or practice audit (Wolfson, Trebilcock et al., 1980).

In the UK, both the GOsC and the GCC will invoke a disciplinary process if a practitioner receives a criminal conviction or is accused of unacceptable professional conduct. They will also investigate cases where a practitioner is believed to be professionally incompetent or whose physical or mental condition impairs practice or makes them unable to practise properly (Allsop, Jones et al., 2004). The process for screening complaints, investigating and adjudicating on cases differs among statutory regulators. Both the GCC and the GOsC have recourse to a range of sanctions including erasure or suspension from the register, conditional registration or giving a warning/caution to the registrant (Allsop, Jones et al., 2004). In Norway, CAM practitioner associations seeking registration are required to have in place statutes which include ethical rules and professional responsibilities.

3.5 Self-regulation

Self-regulation is when a group of individuals (or firms) exert control over the behaviour and activities of their membership, or when an organisation or association develops “a system of rules that it monitors and enforces against its own members” (Baldwin and Cave, 1999, p39). There are a number of ways in which approaches to self-regulation vary:

- Level of state intervention: self-regulation may be subject to government oversight or structuring;
- Legal enforcement of standards and rules: regulation may operate in an informal, non-binding and voluntary manner or may involve rules which are enforceable in a court of law (Baldwin and Cave, 1999, p126);
- Extent of functional delegation: all or only some regulatory functions may be delegated to the self-regulating body;

- Scope of application: regulations may apply to all those in the sector or only those who join an association voluntarily.

In countries where the practice of CAM is not illegal for non-licensed practitioners, there are numerous voluntary professional associations which set and monitor standards of practice, including codes of ethics. In Victoria, Australia there is consensus that standards of practice for conventional health care practitioners who incorporate CAM therapies into their practice should be established through guidelines and codes of practice rather than legislation. In the UK, there is a bewildering array of voluntary professional associations purporting to represent CAM practitioners most of which set some requirements for membership (see Chapter 4).

Baldwin and Cave (1999) identify a number of ways in which governments might constrain self-regulation: statutory rules, oversight by a governmental agency, systems in which ministers approve or draft rules, procedures for public enforcement of self-regulatory rules and mechanisms of participation or accountability (Baldwin and Cave, 1999, p126). Statutory self-regulation can be characterised as the establishment of an independent agency (the regulator) whose rules of operation are set down in statute, whose membership is dominated by representatives of the providers, and whose decisions are subject to appeal in the courts or another superior public agency (Ogus, 2002). Statutory self-regulation has also been called “enforced self-regulation” (Ayres and Braithwaite, 1992, pp101-132).

Self-regulation is found in a number of sectors, including the press (e.g. Press Complaints Commission), financial services (e.g. Financial Services Authority), and advertising (e.g. Advertising Standards Authority) (Baldwin and Cave, 1999, p125). Professional groups such as lawyers and teachers have also traditionally enjoyed devolved responsibilities for regulating their own affairs. Wolfson, Trebilcock et al. (1980) argued that the decision to delegate the administration of regulation to professionals should only occur if there are “high costs of error, information, and enforcement and a need to reinforce trust between practitioners and clients” (Wolfson, Trebilcock et al., 1980, p212). It is not evidence that these all hold in the case of CAM practitioners.

Internationally enforced or statutory self-regulation has been almost universally applied to medical practitioners. The relationship between state and profession which relies on trust has come under increasing strain as information on performance has become more widely available and both the costs and quality of services subject to greater scrutiny (Tuohy, 2003). Statutory self-regulation is also the most common model of regulation for CAM practitioners internationally.

Statutory self-regulating bodies for specific CAM therapies have been established in the UK (the GOsC and the GCC), Hong Kong (the Chinese Medicine Council), India (the Central Council of Indian Medicine and the Central Council of Homoeopathy), and Singapore (the Traditional Chinese Medicine Practitioners Board). Ghana (in 2000) and South Africa (in 2004) have both introduced legislation to establish umbrella statutory councils to register and license traditional health practitioners (Dixon, 2007 forthcoming).

3.6 Incentives

The use of financial incentives by the state to affect the behaviour of individuals, groups or firms can be seen as a form of regulation. This is usually through the imposition of negative or positive taxes, or by deploying grants and subsidies from the public purse (Baldwin and Cave, 1999, p42). Negative taxes would be the levying of higher taxes on a good or service in order to reduce the demand for that good or service. Positive taxes are used to encourage activities that are seen as socially beneficial, ensuring levels of consumption of goods or services with positive externalities, or lowering financial barriers to items which are necessary or essential goods. Positive taxes can be in the form of tax allowances (an amount of income or expenditure exempted from tax), tax relief (expenditure allowed to be deducted from gross income before tax is charge), or a tax credit (a deduction from an individual's or household's tax liability) (Commission on Taxation and Citizenship, 2000, p259).

There is little information available on the extent to which incentives are used to influence the behaviour of providers or consumers of CAM services. In some countries, out-of-pocket health care expenditures are tax deductible. It is possible that if a broad definition of 'health care' is used that money spent on consultations with CAM practitioners could be included. In the UK membership fees to join professional associations are tax deductible, as are the fees paid to statutory regulators, so CAM practitioners are able to benefit from these subsidies.

3.7 Market harnessing controls

There are a number of regulatory mechanisms which use the market to effect the behaviour of firms, rather than impose bureaucratic controls. These include competition laws, franchising, tradable permits and contracting. Neither franchising nor tradable permits are directly applicable to the CAM market. Franchising is used in naturally monopolistic markets such as broadcasting and railways. Tradable permits are generally

used to limit the overall number of producers, thus creating a market in permits. Licensure is used to control access to the market in professional services (discussed above).

3.7.1 *Competition laws*

Competition laws may be used to ensure sufficient competition in order that adequate services are provided, or to prevent anti-competitive behaviour particular in monopolistic or oligopolistic markets. The enforcement of these laws usually relies on court actions being brought by other firms or by government competition authorities.

In most countries, as in the UK, practitioners are self-employed or operate as small businesses so the market tends to be highly competitive. However, the creation of a single register controlled by the profession together with protection of title means that the profession holds a *de facto* monopoly of services. There have been a number of investigations and reports by competition authorities into the market for professional services in the UK (Monopolies Commission, 1970; Office of Fair Trading, 2003). A self-imposed advertising ban by registered medical practitioners was challenged by the competition authority (Monopolies and Mergers Commission, 1989a) as were restrictions on advertising by professionally registered osteopaths (Monopolies and Mergers Commission, 1989b). The Commission recommended that:

advertisements should be in accordance with the principles of the British Code of Advertising Practice, should contain nothing which would reasonably be regarded as likely to bring the profession into disrepute, and should not be such as to abuse the trust of potential patients or exploit their lack of knowledge (Monopolies and Mergers Commission, 1989b).

The GOsC has followed these recommendations and included in its code of practice that “All advertising must be legal, decent, honest and truthful and must conform to the current guidance, such as the British Code of Advertising Practice” (General Osteopathic Council, 2005). The GCC has issued similar guidance (General Chiropractic Council, 2005a).

3.7.2 *Regulation by contract*

Contracts between the government (or its agencies) and private parties can be used to achieve certain regulatory objectives. By using their spending power and specifying terms and conditions in contracts they are able to exercise control over the activities of private parties (Baldwin and Cave, 1999, p46). In addition patients enter contracts with private providers of services and employers enter into employment contracts with employees, all of which are legally enforceable.

Practitioners who are regulated or licensed are not automatically eligible for reimbursement from public or private insurers. Contracts with providers and with members (i.e. insurance policies) can be used to determine the requirements that must be met in order for CAM practitioners to be eligible for payment. In the USA both public and private insurers specify limits to the amount, type of benefit or type of provider (e.g. only medical doctors who also provide acupuncture) which they cover (Dower, 2003). Despite chiropractors being licensed in every state, about 50 percent of health maintenance organisations and 75 percent of private health insurance plans cover chiropractic services (Meeker and Haldeman, 2002). Public insurers also use their purchasing power to specify what services are eligible for reimbursement. For example Medicare cover includes chiropractic and massage therapy for back trouble, and biofeedback for muscle re-education. Acupuncture is currently under consideration (Bodeker, Ong et al., 2005).

In Germany sickness funds only reimburse visits to a doctor not to a *Heilpraktiker*, the exception being partial reimbursement of some *Heilpraktiker* costs by the state-run financial assistance scheme for public officials including teachers, policemen, etc. Many private insurance plans cover visits to a *Heilpraktiker* and complementary insurance packages may offer coverage for naturopathy including *Heilpraktiker* treatment.

In England, Primary Care Trusts (PCTs) are currently responsible for purchasing services and holding contracts with providers, including with homeopathic hospitals and with integrated primary health care providers, where these exist. In addition, some NHS providers have employment contracts with CAM practitioners. A patient who buys treatment from or pays for a consultation with a CAM practitioner in the private sector enters a contractual relationship which is legally enforceable (Department of Health, 2000b, p104).

3.8 Disclosure

Rules governing disclosure, data protection, confidentiality and content of information (in particular advertising, labelling and marketing) are all well-established regulatory tools. Regulation concerning the disclosure of information may be either prohibitive or enabling. For example, regulation might prohibit the disclosure of misleading or false information, or require mandatory disclosure of information to consumers on price, composition, quantity, or quality. Rather than requiring producers to disclose information the government, regulator, or consumer associations may provide information to consumers directly (see below).

Prohibition of false marketing claims for health products and services apply to CAM practitioners. In Germany regulations prohibit *Heilpraktiker* from claiming to treat communicable diseases. In Norway, regulations for advertising by CAM practitioners were set out in new government regulations. In the UK, under the Cancer Act 1939 it is a criminal offence to 'advertise' (by any written or oral statement) offering to treat, to provide a remedy for, or to give any advice in connection with the treatment of cancer (Trading Standards Institute, 2006). In addition the Advertising Standards Authority upholds a voluntary code of practice (the British Code of Advertising, Sales Promotion and Direct Marketing) which contains specific rules governing health claims.

Positive disclosure acts are also common. Practitioners may be required to disclose sufficient information to the patient to enable them to make a fully informed choice. In the UK any health professional, including CAM practitioners, should disclose information regarding risks, possible side effects and treatment alternatives, and gain specific consent for procedures which are more intrusive (Stone and Matthews, 1996, pp178-9).

Regulations may also require CAM practitioners to publish information on qualifications held, length of training, membership of any professional bodies, price of services, or proof of valid insurance cover for liability. Such information may be deemed important to ensure that consumers can compare services and judge the quality of the service being provided. In Portugal registered CAM practitioners are required to display information concerning the price, duration and prognosis of therapies (Erdsal and CAM-CANCER Consortium, 2005).

3.9 Direct action

The direct provision of goods or services using government resources is common for public goods (that is goods and services which have large externalities and are non-rival and non-excludable). In some countries health care has been provided under this model, whereby the state owns the facilities and employs those who provide health care services. In the UK, CAM services are not usually provided in this way. An exception are homeopathic services which were nationalised when the NHS was established in 1946, (see Chapter 2). In China, Korea and Vietnam traditional systems of medicine are fully integrated as part of the public systems of health care (Bodeker and Kronenberg, 2002; World Health Organization, 2002).

Another form of direct action is the provision of public education. Courses may be provided directly through state funded universities or higher education programmes. The quality of the training provided is usually subject to external standards, accreditation and

inspection. For example in Japan all institutions and colleges providing CAM training must be authorized either by the Ministry of Health, Labour and Welfare or the Ministry of Education, Culture, Sports, Science and Technology.

The government may also provide information directly to patients and the public. The Department of Health in England has funded a patient guide to complementary therapy by the Foundation for Integrated Health (Pinder, 2005). Otherwise consumer organisations are the main source of independent information about CAM practitioners, providing information on where to find a qualified practitioner and what questions to ask (Which?, 1999).

3.10 Rights and liabilities laws

This form of regulation works by distributing rights to consumers and giving providers associated liabilities. The potential costs of damages act as a deterrent to harmful activities. Insurance against damages may reduce the incentive of the providers to comply, as they will not face the costs of potential damages. However, if the costs of insurance are very high it is more likely that cases will have to resort to the law, and damages be paid by the producer.

Under common law in the UK, all practitioners have a duty of care towards their patients (Department of Health, 2000b, p104). A patient therefore has the right to sue a practitioner for negligence. In such a case a patient must prove that the practitioner owed the patient a duty of care, that this was breached, and as a result the patient suffered (Stone and Matthews, 1996). There is, however, a dearth of specific CAM-related case law. This may be due to the low number of cases that are taken to court (practitioners would rather settle out of court), or because of other factors which make CAM practice less litigious. Possible reasons might include the high levels of trust between patient and practitioner, low occurrence of adverse outcomes, or the difficulties of establishing the burden of proof that a particular outcome was caused by a specific treatment.

Even if a patient is successfully able to sue, if no assets are held they will not receive any compensation. Insurance is mandatory for CAM practitioners in Iceland, Norway, Portugal, and Sweden.

3.11 Public compensation

These are no fault liability schemes under which the complainant gives up the right to sue in return for compensation. The aim of these schemes is to reduce litigation costs. No specific examples were identified relating to CAM.

3.12 Discussion

This chapter has identified a vast range of regulatory options available to policymakers which could be used to regulate CAM practitioners. Regulation is commonly understood to involve legislative action or use of other statutory instruments by the state. Employing a broader definition has highlighted the way in which governments can also use their economic power, for example through tax incentives, contracting or direct action, and can control or encourage the provision of information through rules of disclosure. Many of these other strategies are used to regulate the practice of CAM in other countries. In the UK CAM practitioners are subject to the provisions of general regulations but these strategies have not been used specifically to regulate CAM. As we shall see in subsequent chapters, policymakers have limited debate to the introduction of statutory self-regulation for specific CAM practitioners. It is puzzling that given the potential of some of these alternative strategies they have not been given due consideration.

There is a wealth of international experience of how to regulate CAM practitioners. Several countries, including Norway, which have either introduced or plan to introduce legislation to legalise and regulate the practice of medicine by non-medical practitioners established Commissions or independent reviews to examine international experience. It is surprising that neither the House of Lords' Sub-Committee nor the UK government commissioned any systematic exploration of approaches to the regulation of CAM practitioners in other countries to inform its deliberations and proposals.

While examples from other countries are useful to demonstrate the possibilities, direct translation of such regulations is unlikely to prove successful. CAM traditions vary widely between countries, even within Europe. For example anthroposophic medicine is widely practised in both Germany and the Netherlands while in the UK it remains a minority therapy not usually included as a distinct category in surveys. The legal status of CAM practitioners also reflects the wider legal system. In countries with civil or Napoleonic law unless explicitly permitted in law the practice of medicine is illegal for anyone other than medical practitioners. In contrast in countries with common law traditions the legal environment has historically been more permissive of CAM practise. Models of regulation must therefore be consistent with the general legal structure, and historical and cultural norms.

I come back to consider some of these alternative strategies in the concluding chapter. The next chapter reviews the historical development of professional regulation in the UK and how this has shaped the regulation of CAM.

4 THE HISTORY OF HEALTH CARE PROFESSIONAL REGULATION

4.1 Introduction

The recent history of the regulation of complementary and alternative medical (CAM) practitioners examined in this study is the latest chapter in a story which stretches back at least to the mid-19th century. Prior to the 1850s provision of health care in Britain was not formally regulated by the state (Porter, 1989). There were many small-scale business entrepreneurs practising medicine and charging for their services. Medical pluralism flourished. As Lindemann (1999) observed:

The landscape literally swarmed with them [practitioners] in every conceivable form: physicians, surgeons, midwives, cunning folk, bone setters, dentists, lithotomists, bathmasters, apothecaries, pastors and ordinary people who busied themselves with medicine either as part of their normal household chores or as expressions of good neighbourliness (Lindemann, 1999).

At this time the term ‘quack’ was commonly used to refer to those who peddled miracle cures at exorbitant prices (Porter, 1983). Later it would come to be applied to anyone practising medicine outside the medical orthodoxy of biomedicine (Wahlberg, 2005).

The Medical Act 1858 granted statutory powers to doctors to self-regulate their profession. Prior to this the Royal Colleges had exercised regulatory powers over their members, but membership was voluntary. The Act did not restrict the common law right to practise medicine and CAM therapies continued to flourish. Despite efforts to prevent other health care occupations from securing similar legal protections pharmacists, dentists, opticians, nurses and midwives, and professions allied to medicine successfully gained statutory regulation over the course of the 20th century. It was not until the early 1990s that any complementary medical practitioners gained statutory regulation.

The events studied here did not come out of the blue, but followed on from earlier attempts to gain statutory regulation by the osteopaths, the chiropractors and the herbalists. Before providing an account of the experiences of each of the five therapies to be examined in this study - acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy - the chapter highlights the main events in the history of health care professional regulation.

Section 4.2 briefly summarises the experience of the medical profession in 1858 in overcoming differences within the profession between the elites represented by the Royal Colleges and the provincial practitioners. Section 4.3 traces the struggles that other health care practitioners experienced to achieve their own legislative protections in the face of medical opposition. Finally Section 4.4 provides an account of the activities of CAM practitioners prior to the 1990s and identifies the key historical milestones in their development as a profession.

4.2 History of medical regulation

4.2.1 *The Royal Colleges*

In the period prior to the Medical Act 1858 voluntary self-regulation was dominant. The Royal College of Physicians in London was created by Royal Charter in 1518 by Henry VIII. By 1550 there were three corporations in London: the Society of Apothecaries, the Barber-Surgeons Company, and the College of Physicians, which flourished or faded depending on monarchical patronage (Lindemann, 1999). The Royal College of Physicians London served a number of purposes as a learned society, a representative organisation, and a sanctioning agency (against malpractice and illicit practice). In this early period of regulation physicians used the Parish Constable to enforce rules and impose sanctions, stating that “none shall practice Physick without License of the College, on pain of forfeiting five pounds a Month”. Exemption was made for “Persons having Knowledge in Herbs, etc.” who were permitted to treat sores and administer oral medicines (Fox, 2002).

The Royal Colleges also specified the expected standards of knowledge and training required by practitioners. For example the Royal Charter of the Barber-Surgeons of Edinburgh in 1506 stated:

... that no manner of person occupy or practise any points of our said craft of surgery... unless he be worthy and expert in all points belonging to the said craft, diligently and expertly examined and admitted by the Maisters of the said craft and that he know Anatomy and the nature and complexion of every member of the human body... for every man ocht to know the nature and substance of everything that he works or else he is negligent (cited in Royal College of Surgeons of Edinburgh, 2005).

Royal colleges have continued to play a significant role in ensuring the standards of training. Since September 2005 the Postgraduate Medical Education and Training Board has assumed some of these responsibilities (Department of Health, Scottish Executive et al., 2003).

Despite the strength of the Royal Colleges many practitioners continued to practise medicine outside the scope of the Colleges. An early challenge to the Royal Colleges came from an apothecary. In 1704 the House of Lords ruled in favour of William Rose and deemed that apothecaries could also practice medicine though they were not permitted to charge for attendance so depended on the drugs they dispensed for their income (this is explored further below) (Lindemann, 1999). As Lindemann notes, “members of medical corporations by no means monopolized (or even dominated) the medical marketplace. Literally thousands of non-corporate practitioners thrived” (Lindemann, 1999, p174).

4.2.2 *The Medical Act 1858*

As we shall see in later chapters the lack of consensus among CAM practitioners is often cited as a barrier to statutory regulation, yet the medical profession was not united prior to the achievement of statutory regulation (Muirhead Little, 1932, p3). Disputes within the Company of Barber-Surgeons (established in 1540) resulted in the surgeons breaking away and forming the Company of Surgeons in 1745. Interests in statutory regulation were also divided between specialists and general practitioners, the elite based in London and doctors working in provincial towns and cities, and those trained at universities and those trained at private schools. This fragmentation within the profession resulted in lengthy debates prior to the Medical Act 1858.

The medical reform debate raged throughout the 1830-50s. The British Medical Association (BMA),⁸ originally founded as the Provincial Medical and Surgical Association in 1832, created the Medical Reform Committee to lobby on behalf of its members for a unified examining and licensing authority (Muirhead Little, 1932). The first Medical Reform Bill was introduced in 1840. It proposed that the title ‘qualified medical practitioner’ be conferred only on those with qualifications in all the major branches of medicine. These proposals were opposed by the Royal Colleges who wanted to maintain specialist practice.

The Act to establish the General Council of Medical Education and Registration (shortened to the General Medical Council (GMC) in 1951) empowered nineteen universities and nine medical corporations (i.e. the Royal Colleges) to grant licences to practise medicine under the supervision of the GMC (Eckstein, 1960). The Act strengthened and unified the medical profession after several centuries of internal divisions epitomised in the disputes between the Royal Colleges. As Stacey (1992) notes:

⁸ In the context of professional regulation it is useful to note the difference between representative bodies and regulatory bodies. For example, the British Medical Association is the representative body acting as a trade union for doctors, whereas the General Medical Council is the regulatory body responsible for registering qualified practitioners.

[The Act] led to the development of a self-conscious occupation aiming for control of work situation and client, controlling its own labour supply and its own remuneration...the Council was in a position to establish standards of intra-professional conduct backed up by disciplinary procedures, and thus to begin to develop a national system of medical ethics
(Stacey, 1992, pp 18-19)

Entry to the register initially required an arts degree and four years of professional practice. There were as many as 22 different diplomas permitting registration (in addition to the numerous domestic and overseas degrees permissible for those already in practice) (Chief Medical Officer of England, 2006). These transitional arrangements permitted 'grandfathering' enabling those who were currently practising to enter the register without having to re-qualify. In 1867 ten medical subjects were made obligatory for teaching and examination, but these only became mandatory for registration in 1886. The Medical Act 1886 also established the requirement that registrants should have dual qualifications as a surgeon and physician.

The establishment of the GMC and a medical register was a political victory for those in the medical profession who had lobbied for medical reform. Registration created a monopoly over public and statutory duties, with exclusive rights to work in government medical services and paved the way for greater political influence of the medical profession (Eckstein, 1960). The Medical Act 1858 was a compromise between the interests of different factions within the medical profession. It was the beginning, rather than the culmination, of a process of consolidation and unification. Many changes in the constitution and responsibilities of the GMC have taken place through successive Medical Acts and Orders of the Privy Council, too numerous to detail here (see Stacey, 1992 for a fuller historical account of the GMC).

The Medical Act 1858 is portrayed in some historical accounts as a watershed that banished alternative medicine to the fringes and contributed to its decline. And yet it did not restrict the practice of medicine, only the use of the title 'registered medical practitioner'. The demand for unqualified practitioners continued to flourish in part because those practitioners who had been educated in medicine at universities were not widely respected, and their practices were unaffordable and inaccessible to the majority of the population (Porter, 1989). Non-allopathic therapies continued to be practised both by registered medical practitioners and non-registered practitioners throughout this period. More recent accounts therefore reject the idea that CAM therapies went into decline during the late 19th century and early 20th century (Goldstein, 1999; Johnston, 2004). Such accounts are

mirrored by histories of the medical profession which date its dominance not to the Medical Act 1858 but the NHS Act 1946 (Eckstein, 1960).

4.3 Statutory regulation of other health care professionals

It is important to remember that at the turn of the 20th century, all practitioners providing health care to the public other than doctors were unregulated. Some authors contend that “The frontiers between orthodox and unorthodox medicine have [always] been flexible...So mobile have been their boundaries, that one age’s quackery has often become another’s orthodoxy” (Bynum 1987, cited in Lindemann, 1999). Put another way, today’s orthodoxy is yesterday’s quackery. According to Porter (1994):

The boundaries between fringe and core medicine have been contingent, fluid and negotiable...the distinction between quackery and orthodoxy is essentially social. Quacks are those doctors excluded from professional power and privilege (Porter, 1994, p65).

Health care professionals that are accepted today as part of mainstream medicine were not always considered as such. The gradual extension of statutory regulation to other groups of health care practitioners during the 20th century has shaped the boundaries which today define what we consider to be complementary and alternative medicine. These brief accounts of the efforts of midwives, nurses, dentists and apothecaries to gain statutory recognition provide some interesting parallels with the contemporary experience of CAM practitioners.

4.3.1 Midwives

The struggle between midwives and doctors over rights to attend births was fiercely contested in the 19th century. In some countries doctors successfully denied midwives their independent authority, but their subordination to the medical profession was resisted in the UK. This has been well-documented by Ward (1981) and the following draws heavily on that account. In 1872 the London Obstetrical Society introduced a certificate for midwives who could demonstrate minimum competence, but few women qualified. To rectify the situation the Matrons Aid or Trained Midwives’ Registration Society was established in 1881 (later the Midwives’ Institute {1886} and the Royal College of Midwives {1947}). Its aims were to promote the training of midwives, maintain a register of certified midwives, and provide professional support. By 1886 the Institute was actively lobbying parliament for a Midwives Act and formed a sister organisation, The Association for Promoting the Compulsory Registration of Midwives, to facilitate the campaign. A draft bill was prepared and presented to parliament in 1890 but lack of interest among (male) politicians meant

this and further attempts in subsequent years (1891, 1895, 1896, 1897, 1898, 1899 and 1900) were given low priority in the ballot for Private Members' Bills, or delayed, or defeated (Ward, 1981).

Despite opposition a House of Commons Select Committee was set up to look into the issue in 1892. In evidence the GMC supported registration and the report proposed the GMC draw up rules for the compulsory registration of midwives. There was a backlash from rank and file doctors, particularly provincial doctors, who relied on deliveries for a substantial part of their income. They coalesced into a more organized opposition and were successful in keeping the Act off the statute books. Medical opposition to the Bill culminated in widespread refusal to attend births following a midwife, even when there were complications, resulting in a series of maternal and child deaths. These cases received publicity in the press and catalysed public support for the situation to be resolved through parliamentary approval of the Midwives Bill (Ward, 1981).

The Midwives Act passed in 1902 made it a criminal offence to practise midwifery without certification subject to a fine issued by the courts. A midwife was defined as one who practiced 'habitually or for financial reward' (this allowed the 'friendly neighbour' to attend a birth without fear of prosecution) (Stevens, 2002). A 'grandfathering' clause allowed unqualified practice to continue until 1910 to enable sufficient midwives to gain training. The Central Midwives Board was responsible for maintaining the register, establishing the standards for entry to the register (including setting an examination), and had powers to remove a woman from the register. Any changes to its regulatory powers were subject to approval by the Privy Council (a concession to the midwives who opposed subordination to the GMC as proposed in earlier versions of the Bill). Until the establishment of the NHS local authorities were charged with the local supervision of midwives and had to investigate allegations before referral to the Central Midwives Board (Stevens, 2002).

4.3.2 Nurses

The success of the Midwives Act 1902 galvanised the nursing profession. A bill to introduce state registration of nurses lay before Parliament annually between 1904 and 1914. The historic events surrounding the statutory regulation of nurses have been reported elsewhere (Abel-Smith, 1960) and are briefly summarised here.

The nurses were divided over proposals for state registration. The British Nurses Association (BNA) led by Mrs Bedford Fenwick thought nursing should only be for the daughters of the higher social classes. The BNA established a register where the minimum standard for entry was three years of training. Given that of 64,000 nurses in practice only

20-25,000 had training it is not surprising that the membership of the BNA remained small. Meanwhile the Hospitals Association, Florence Nightingale and nursing matrons were against state registration. They wanted to ensure access to nursing for all social classes, secure recognition for practical training, and resist external interference. The war brought social changes, such as women's right to vote, and saw untrained volunteers working as nurses. Concern among professional nurses about untrained nursing staff united them in demanding a register.

The Nurses Registration Act was passed in 1919 to establish a General Nursing Council. Disputes continued about the rules to admit existing nurses to the register. Consequently parliament intervened in 1923 shortly before the register was due to close. As Abel-Smith (1960) recounts:

Nearly every major decision in implementing the Nurses Registration Act was taken not by the General Nursing Council but by the Minister of Health or the House of Commons. Parliament intervened to preserve the rights of unqualified nurses. The Minister refused to enforce the recommended syllabus of training (Abel-Smith, 1960, p113).

As a result of the divisions within the nursing profession the state had to play a proactive role in the regulatory process.

4.3.3 Dentists

Dentistry developed from a medical specialty and its regulation emerged gradually so was not opposed by the medical profession. In the early part of the 19th century there was no unity, organisation or code of ethics among those who practised dentistry. The first organised professional associations were formed in 1856; the Odontological Society represented dental surgeons and the College of Dentists of England represented other general dental practitioners. The Dental Reform Committee, formed in 1875, lobbied for a registration bill which would give the dental profession legal recognition. This was achieved in the form of the Dentists Act 1878 which established a Dentists' Register (operational in 1879) and granted protection of title. The Act stated that:

a person shall not be entitled to take or use the name of dentist... or dental practitioner, or any other name, title addition or description implying that he is registered under this Act, or that he is a person specially qualified to practise dentistry unless he is registered under the Act (cited in Forbes, 1985).

The Register and regulatory functions were performed by the GMC. With the establishment of the Dental Board in 1921 dentists obtained protection of function,

something medical practitioners have never achieved. The Board continued to share responsibility for educational and ethical control of the profession with the GMC. It was only with the creation of the General Dental Council in 1956, following the recommendations of the Teviot Committee report (1946) and the Dentists Act 1956, that dentists gained full autonomy from the medical profession (Forbes, 1985).

4.3.4 *Apothecaries*

The Apothecaries Act 1815 followed a period of agitation during which time the boundaries between the activities of apothecaries, surgeons, physicians, and chemists or druggists were contested and several draft bills and proposals were debated. Apothecaries were widespread throughout the country and offered the only affordable means for the poor and lower classes to receive medical care; they were akin to a general medical practitioner. Trained apothecaries, represented by the Society of Apothecaries, felt they were being encroached upon by chemists and druggists who were taking over the dispensing of drugs and compounds, including those prescribed by physicians, and undermined by unqualified and unskilled people trading as apothecaries (Holloway, 1966).

Restrictions on the right of apothecaries to charge patients for attending (dating from a case taken to the Lords by the College of Physicians in 1703) meant they had to obtain their income from charging for the drugs dispensed. Early proposals by the General Pharmaceutical Association attempted to restrict dispensing rights to apothecaries. The Associated Faculty proposed that educational standards should be set for all practitioners of medicine, and that qualified practitioners should be required to register, in an attempt to elevate apothecary to a profession. The Associated Apothecaries and Surgeon-apothecaries proposed to allow practitioners to charge for attendance (a concession the physicians were unwilling to accept).

The Apothecaries Act 1815⁹ reflected the interests of the College of Physicians in that it subordinated apothecary under the direct supervision of the College and reinforced its characteristics as a trade rather than a learned profession. The Act allowed those already practising to continue to do so. New practitioners had to pass an exam following a five year apprenticeship, and present testimonials of medical education and 'good moral character' in order to obtain a licence (Holloway, 1966, p125). When the Pharmaceutical Society was granted Royal Charter in 1853 it signalled the beginning of the demise of the Society of Apothecaries.

⁹ The full title was 'An Act for enlarging the Charter of the Society of Apothecaries in the City of London, granted by His Majesty King James the First, and for better regulating the Practice of Apothecaries through England and Wales'.

Throughout the 19th and early 20th century, non-medical health care practitioners have sought state protection for their practice through an Act of Parliament. Such legislative activities have often brought them into conflict with the orthodox medical profession as well as other health care practitioners particularly where occupational boundaries overlap. These accounts of the struggles within and between professional groups have many parallels among CAM therapies as we shall now see.

4.4 History of the regulation of complementary and alternative medical practitioners

The 20th century saw the introduction of a number of new therapies to Great Britain and a proliferation of private schools and colleges. Practitioners established their own professional associations (see Table 4.3) and academic journals. Therapies developed their own ontology and epistemology and set themselves in opposition to ‘allopathic’ medicine. The following sections describe briefly the main professional and regulatory developments that have taken place in acupuncture, chiropractic, herbal medicine, homeopathy, and osteopathy (see Appendix 1 for a brief description of the therapies and their uses).

4.4.1 *Acupuncture*

There was some interest in acupuncture in the early to mid-19th century when it was first introduced to Europe from China and Japan. In England, interest was fuelled by the publication of a monograph ‘On Acupuncturation’ in 1821 by a young surgeon called James Churchill. By the end of the decade use of acupuncture was fairly widespread in private practice and in the great London hospitals (Acupuncture Regulatory Working Group, 2003). In spite of this promising start acupuncture went into decline after 1828, and was marginalized in Britain until a revival in the 1950s and 1960s led by British physician Felix Mann, who had been taught the technique in Paris (Saks, 1995; Baldry, 2005). In the early 1970s it received widespread publicity for its use in China as an anaesthetic as a result of President Nixon’s visit there in 1972, and gained legitimacy with the medical profession due to advances in the understanding of pain (Saks, 1986).

Table 4.3 Development of voluntary professional bodies for acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy, year established

Profession	Associated bodies	Year established
Acupuncture	British Acupuncture Association and Register	1961-1995
	International Register of Oriental Medicine	1972-1995
	Traditional Acupuncture Society	1976-1995
	Register of Traditional Chinese Medicine	1979-1995
	Modern Acupuncture Association	1981-
	Council for Acupuncture	1980-1995
	Fook Sang Acupuncture & Chinese Herbal Practitioners Association	1983
	British Acupuncture Accreditation Board	1989- present
	British Acupuncture Council	1995-present
	European Federation of Modern Acupuncture	1996-present
	British Medical Acupuncture Society	1980-present
	Acupuncture Association of Chartered Physiotherapists	1984-present
	British Academy of Western Acupuncture	1976-present
Chiropractic	British Chiropractic Association	1925-present
	Scottish Chiropractic Association	1972-
	John McTimoney Chiropractic Association	1979-1981
	Institute of Pure Chiropractic	1981-1994
	British Association for Applied Chiropractic	1984-present
	McTimoney Chiropractic Association	1994-present
Herbal Medicine	National Institute of Medical Herbalists	1864-present
	British Herbal Union	1940s? -1960
	General Council and Register of Consultant Herbalists	1960 - 1997
	Association of Master Herbalists*	
	British Society of Chinese Medicine*	
	Register of Chinese Herbal Medicine	1987-present
	International Register of Consultant Herbalists	1943-1997
	International Register of Consultant Herbalists and Homeopaths	1997-present
	Unified Register of Herbal Practitioners	1997-present
	Association of Traditional Chinese Medicine	1994-present
	Ayurvedic Medical Association*	
	British Association of Accredited Ayurvedic Practitioners*	
	British Ayurvedic Medical Council*	
	European Herbal Practitioners Association	1993-present
Homeopathy	British Homeopathic Society	1843-1944

Profession	Associated bodies	Year established
Osteopathy	Faulty of Homeopathy	1944 -present
	Society of Homeopaths	1978-present
	Alliance of Registered Homeopaths	2001-present
	Homeopathic Medical Association	1985 -present
	International Register of Consultant Herbalists and Homeopaths	1997-present
	Joint Meeting of Organisations Registering Professional Homeopaths	1999-2000
	Council of Organisations Registering Homeopaths	2000-present
	British Society of Osteopaths	Pre 1911
	British Osteopathic Association	1911* -present
	Incorporated Association of Osteopaths Ltd	1925 -1936
	Osteopathic Association of Great Britain	1936-1992
	British Naturopathic and Osteopathic Association	1961-1998
	Guild of Osteopaths	1971-1998
	General Council and Register of Osteopaths	1936-1993
	College of Osteopaths	1948
	Natural Therapeutic & Osteopathic Society	1948
	British and European Osteopathic Association	1976
	Association of Osteopathic Practitioners	1984
	Faculty of Osteopathy	1978
	Osteopathic and Naturopathic Guild	1967

Sources: Various including (Monopolies and Mergers Commission, 1989b), (Mills, 1993), (Baer, 1984), websites and personal communication.

* Details on the history of many of the smaller professional associations was not available.

Mann held regular meetings which gave birth to the British Medical Acupuncture Society (BMAS), formally established in 1980. The launch of its scientific journal 'Acupuncture in Medicine' followed in 1981. The BMAS established regular teaching courses for doctors leading to professional qualifications. In 1990 a standardisation of the meridian nomenclature was published, further establishing the medical-scientific basis for acupuncture practice (Baldry, 2005). It later extended its scope to include nurses, physiotherapists, osteopaths, chiropractors, health visitors, midwives and podiatrists as members (British Medical Acupuncture Society, 2004). Growth in interest and practice among physiotherapists led to the establishment of the Acupuncture Association of Chartered Physiotherapists (AACP) in 1984. The British Academy of Western Acupuncture (BAWA) was established in 1976 to teach medical doctors, registered nurses and chartered physiotherapists western acupuncture. Today it predominantly trains and represents nurses (British Academy of Western Acupuncture, 2000).

The practice of acupuncture by non-medically qualified practitioners in the UK dates back to at least the 1960s, when private colleges opened offering longer and more intensive courses in traditional acupuncture. Several societies were formed to represent the graduates of these colleges: the British Acupuncture Association and Register in 1961, the International Register of Oriental Medicine in 1972, the Traditional Acupuncture Society in 1976, and the Register of Traditional Chinese Medicine in 1979. In 1980 these societies together with the Chung San Acupuncture Society (CSAS) formed the Council for Acupuncture to co-ordinate standards of training and codes of ethics and practice (British Acupuncture Council, 2006). In June 1995 the Council for Acupuncture was succeeded by the British Acupuncture Council (BAcC) which unified the five member groups.

Traditional acupuncture was originally learnt by people studying in China. In recent years teachers have come from China to offer acupuncture courses in Britain (Acupuncture Regulatory Working Group, 2003). By the 1990s acupuncture was being taught as a university degree. The British Acupuncture Accreditation Board (BAAB) was established in 1989 to set training standards and accredit training institutions. In 2003 it had accredited seven teaching institutions offering courses in traditional acupuncture, and four further teaching institutions were undergoing accreditation (Acupuncture Regulatory Working Group, 2003).

The Acupuncture Regulatory Working Group (ARWG) was established in 2002 and met for a period of a year under the chairmanship of Lord Chan of Oxton, a paediatrician and the only peer of Chinese descent in the Lords' until his untimely death in 2006. Representatives from four main groups were involved: the BAcC, the BAWA, the BMAS and the AACP. It reported in September 2003 (Acupuncture Regulatory Working Group, 2003). Its key recommendations were that there should be a General Acupuncture Council which should regulate the activities of non-statutorily regulated practitioners of acupuncture, and extend registration (or listing) to statutorily regulated health care professionals who wished to practise acupuncture and use one of the proposed protected titles e.g. 'acupuncturist'.

As later chapters will reveal the historical divisions between medical and traditional acupuncturists have shaped the process of professionalisation and the approach to regulation adopted.

4.4.2 *Chiropractic*

Chiropractic was founded by Dr Daniel Palmer in the USA in the 1890s and was further developed by his son. It was introduced to Great Britain in the early 1900s. The British

Chiropractic Association (BCA) was formed in 1925, and opened the Anglo-European College of Chiropractic in Bournemouth in 1965. In 1988 this became the first complementary medicine college to offer a validated degree course in the UK.

There are two other schools of chiropractic: the McTimoney Chiropractic School (established 1972) and the Witney School of Chiropractic (established 1984) (King's Fund, 1993). Graduates trained at the former are generally members of the John McTimoney Chiropractic Association (established in 1979) which was renamed the Institute of Pure Chiropractic in 1981 and then the McTimoney Chiropractic Association in 1994. Graduates of the Witney School (now the Oxford College of Chiropractic) are usually members of the British Association for Applied Chiropractic (established in 1984).

In the early 1980s the BCA made an unsuccessful attempt to gain statutory regulation through inclusion under the Professions Supplementary to Medicine Act 1960. In 1991 the British Association of Applied Chiropractic, the BCA, and the Institute of Pure Chiropractic, with a combined membership of 785, formed the Chiropractic Registration Steering Group. Its aim was to create unified educational standards through the creation of a European Council on Chiropractic Education. It reported in 1993.

Following the successful passage of the Osteopaths Act 1993 (see below), the chiropractors found support for a similar process to establish statutory regulation through primary legislation. A King's Fund Working Party was established under the chairmanship of Sir Thomas Bingham, subsequently Baron Bingham of Cornhill and Lord Chief Justice of England and Wales 1996-2000, to draw up proposals (King's Fund, 1993). The proposals and a draft bill were published in 1993.

The Chiropractors Bill was proposed to the House of Commons by David Lidington MP as a Private Members' Bill in the 1993-94 session and came fourth in the ballot of members. It had its first reading on 16th December 1993. It received its second reading on 18th February 1994, and was passed after its third reading on 6th May 1994. The Chiropractors Act 1994 led to the establishment of the General Chiropractic Council (GCC). Transitional arrangements were put in place but from 14th June 2001 'chiropractor' became a protected title, and it is now a criminal offence for anyone not registered with the GCC to use it. In June and July 2005 three people were convicted for wrongfully using the title of 'chiropractor' and wilfully misleading the public (General Chiropractic Council, 2005b; General Chiropractic Council, 2005c).

Chiropractic remains the smaller of the therapies included in this study. Even so the profession was historically divided into a number of traditions and schools.

4.4.3 *Herbal medicine*

In Britain traditions of herbal medicinal use are recorded in published herbal pharmacopoeias dating back to the 16th and 17th centuries. Those of Nicholas Culpepper and John Gerard are well known to this day (McIntyre, 2001). Chinese herbal medicine has developed over thousands of years and uses combinations of herbs to address a wide range of health problems. It is now popular in European societies (Ernst and Dixon, 2004). There are other eastern traditions which use herbal medicines, such as Tibb, Kampo, Ayurvedic, Maharishi Ayurvedic, and Unani medicine, as well as traditional African medicine, though these tend not to be widespread outside immigrant communities.

Herbalists were granted rights to practise medicine as early as the 16th century. The public reaction to attempts by doctors to prevent others from practising medicine led Henry VIII to enact the Herbalists Charter 1543 which granted rights to all his subjects to practise herbal medicine (McIntyre, 2001). It was not until the late 19th century and the widespread use of non-plant substances that the distinction between traditional herbalists and druggists and chemists (later to become known as pharmacists) emerged. The National Association of Medical Herbalists¹⁰ was established in 1864 to represent herbalists, with the expectation that herbalists could gain similar professional status as that granted to doctors by the Medical Act (McIntyre, 2001). In 1886 an amendment to the Medical Act and changes to the Poisons Schedule which would have made herbal practice illegal were both defeated. The herbalists attempted to gain a Charter in the 1890s.

In 1923 a Private Members' Bill to introduce statutory regulation of medical herbalists was defeated at its second reading. McIntyre notes that herbal medicine reached its 'nadir' in Britain during the 1950s and 1960s following the establishment of the NHS from which herbal medicine was excluded. Bevan was only willing to incorporate herbalists into the NHS if they were willing to be regulated by and subordinate to doctors. This deal was rejected by the herbalists (McIntyre, 2001). Instead herbalists organised on a voluntary basis. The British Herbal Union (renamed the General Council and Register of Consultant Herbalists in 1960 and then the International Register of Consultant Herbalists and Homeopaths in 1997) established the Faculty of Herbal Medicine in 1949 to provide training opportunities for practitioners.

The Pharmacy and Medicines Act 1941 made the practice of herbal medicine illegal, yet there is no record of any herbalists being prosecuted (McIntyre, 1999). The Act was

¹⁰ "Association" has since been replaced by "Institute".

superseded by the Medicines Act 1968 which overturned the ban. The new Act contained two specific sections governing the availability of herbal medicines:

- Section 12.1 allowed herbal prescriptions to be given without licence following a personal consultation
- Section 12.2 exempted over-the-counter herbal products from licensing as long as they consisted of simple plant mixtures and no health claims were made.

The Act also restricted the use of a list of potent herbs to herbalists.¹¹ These were not allowed to be made available to patients over-the-counter without a licence.

The harmonisation of pharmaceutical licensing within the European Union (EU) threatened to remove the right to dispense herbs from herbalists in the UK. In response a number of professional associations joined together to establish the European Herbal Practitioners Association (EHPA) in 1993. The Medicines Control Agency launched the MLX 206 consultation document on *Harmonisation of UK Medicines Act with European Medicines Directive* in autumn 1994 (Medicines Control Agency, 1994). This proposed that only 'industrially produced' medicines needed to be licensed (in other words herbal preparations were to remain exempt). Successful lobbying, led by the UK government, resulted in a separate EU Directive on Traditional Medicinal Products (2004/24/EC) being passed in April 2004 which took effect in October 2005 (Ernst and Dixon, 2004). This addressed Section 12.2 of the Medicines Act 1968 by requiring industrially produced herbal medicine sold to the public over-the-counter to be included on a positive list, and requiring manufacturers and wholesalers to obtain licences. It left open the issue of how to regulate the dispensing of non-industrially prepared herbal medicines by herbalists under Section 12.1 of the Medicines Act 1968.

The Herbal Medicines Regulatory Working Group was launched on 1st January 2002 under the chairmanship of Mike Pittilo, Vice Chancellor of the University of Hertfordshire, to make recommendations on the regulation of herbalists and unlicensed herbal remedies. It was made up of representatives of the College of Practitioners of Phytotherapy, the Association of Master Herbalists, the National Institute of Medical Herbalists, the EHPA, the British Society of Chinese Medicine, the Register of Chinese Herbal Medicine, the International Register of Consultant Herbalists, the Unified Register of Herbal Practitioners, the Ayurvedic Medical Association, the Association of Traditional Chinese

¹¹ Herbalist was later defined as 'one who exercises his judgment as to the treatment required and accepts legal responsibility for his actions' (McIntyre, unpublished).

Medicine, the British Association of Accredited Ayurvedic Practitioners and the British Ayurvedic Medical Council.

Its recommendations were published in 2003. The preferred option was to establish a CAM Council which would initially register herbal practitioners and acupuncturists but could in future regulate other CAM practitioners. A consultation document MLX299 *Proposals for the reform of the regulation of unlicensed herbal remedies in the UK made up to meet the needs of individual patients* (Medicines and Healthcare products Regulatory Agency, 2004) was launched on 2nd March 2004 together with the Department of Health's proposals for statutory regulation of herbal medicine and acupuncture (Department of Health, 2004a). These discussions coincided with the approval for the first degree course in herbal medicine at Middlesex University (approved 6th May 2004).

As we shall see, reforms to medicines legislation during the 1990s had a major impact on the regulation of herbalists. The different historical roots of herbalists mean they are an extremely diverse profession that embraces both western and eastern traditions. These differences have continued to make unification of herbalists a challenge.

4.4.4 Homeopathy

Homoeopathy was founded by Samuel Hahnemann (1755-1843), based on the Law of Similars (the "like cures like" principle) (National Institutes of Health, 2006). From its German origins in the late 18th century homeopathy proved popular in Britain, particularly among the aristocracy (Morrell, 1999), and during the 19th century was taught in medical schools. The British Homeopathic Society was established in 1843, the British Journal of Homeopathy in 1844, and the London Homeopathic Hospital in 1850. Homeopathy continued to be dominated by medical doctors even after the Medical Act 1858. The Act was successfully amended so that it did not specify the type of medicine to be practised.

Medical homeopathy reached its zenith in the mid-1870s when there were as many 120 homeopathic dispensaries listed in the Homeopathic Medical Directory and 300 homeopathic doctors registered with the Society (Morrell, 1995; Morrell, 1999). Hospitals were established in Glasgow, Bristol and Liverpool. From the 1880s however medical homeopathy went into decline. The Faculty of Homeopathy, which offered postgraduate courses for medical doctors, was only established in 1944 and incorporated in 1950 (replacing the British Homeopathic Society). Homeopathy was integrated into the NHS at its foundation in 1948.

Some radical homeopathic doctors worried by a decline in the practice of medical homeopathy, broke away from the BHS in the early 1900s in order to teach homeopathy to

lay practitioners and home prescribers. The short-lived English Homeopathic Association attempted to popularise homeopathy among the lower classes.

In the 1970s homeopathy was revived as a radical alternative to allopathic medicine, led by two non-medically qualified homeopaths named Maughan and Da Monte. Following their death in 1978 a group of lay homeopaths established a College of Homeopathy, followed by the Society of Homeopaths in 1981. Other colleges were established in the 1980s, only some of which were 'approved' by the Society and therefore whose graduates could gain automatic entry on the register (Cant and Sharma, 1996).

The Joint Meeting of Organisations Registering Professional Homeopaths was established in 1999 with the express aim to "work together for a single register" (Council of Organisations Registering Homeopaths, 2004b). National occupational standards were established together with the Faculty of Homeopathy, which were then approved by the Qualifications and Curriculum Authority and the Scottish Qualifications Authority. The Council of Organisations Registering Homeopaths (CORH) succeeded it in 2000 and agreed its constitution in 2002 with the purpose of representing the interests of those whose primary therapeutic activity is homeopathy and who wish to be identified as homeopaths (Council of Organisations Registering Homeopaths, 2006). The full members of the CORH include three organisations which solely register homeopaths and four which are multi-disciplinary groups.

The CORH launched a consultation document in January 2005 on proposals for a robust system of voluntary self-regulation (Council of Organisations Registering Homeopaths, 2005). The consultation closed in March 2005 and received 1,073 replies. The results of the consultation were presented to the CORH Council on 25th April 2005 before recommendations were proposed to the AGM on 10th June 2005 (Council of Organisations Registering Homeopaths, 2005). The CORH are in the process of devising an implementation strategy for the proposals.

As with acupuncture, the historic division between medical and non-medical homeopaths persists to the present day and shapes the discussion of regulation. Because non-medical homeopathy developed as an alternative to orthodox medicine there is widespread scepticism of orthodoxy of any sort among the leadership of the professional associations. This has coloured their views of statutory regulation, as will be shown in the following chapters.

4.4.5 *Osteopathy*

The practice of osteopathy has its origins in the USA in the 1860s and 1870s. It is based on the principles of osteopathic medicine developed in 1874 by Dr Andrew Taylor Still in response to the ‘excesses of allopathic medicine’, such as the use of strong drugs, bleeding and surgery (Baer, 1984). There are some links between osteopathy and the earlier practices of bonesetters. Indeed, some practitioners learned manipulative therapy in apprenticeships with bonesetters. However, osteopathy in Britain was formally established in the early 1900s by American-trained osteopaths. Over the next century many schools and associations emerged and faded. The picture painted by Baer (1984), on which this section draws, is one of a fragmented profession.

The British Osteopathic Association (BOA) was established in 1911. Six years later the British School of Osteopathy was opened offering a four-year full-time course plus part-time diploma courses. A competing school was opened in 1921, the Manchester College of Bloodless Surgery (later the Manchester College of Osteopathy and Chiropractic). The graduates of this school were not eligible to join the BOA and founded their own association in 1925: the Incorporated Association of Osteopaths Ltd. Over time the Incorporated Association extended its membership to other schools and associations (including the South-Western School of Osteopathy 1929, the British College of Chiropractors, and the National Society of Osteopaths Ltd 1936). It was renamed the Osteopathic Association of Great Britain in 1936.

Only some of these many associations have been actively involved in lobbying for statutory regulation. In about 1914 the BOA applied for registration under the Companies’ Act as a Scientific Society, but this was refused by the Board of Trade. They petitioned the Privy Council in 1931 for a royal charter but were refused due to overly restrictive entry criteria. Private Members’ Bills to establish a register of osteopaths were put before the Houses of Parliament in 1931, 1933 and 1934. The last attempt in 1936 before the House of Lords was supported by the BOA, the Osteopathic Defence League and the British School of Osteopathy. Despite concerns over educational standards the Minister of Health agreed to support the Bill. However, opposition was mounted by the BMA, the GMC, the Royal College of Surgeons of England, the Royal College of Physicians of England, universities and medical schools, and the BCA, and finally supporters of the Bill withdrew it. A Select Committee of the House of Lords, on the advice of the Minister of Health, recommended that the osteopathic bodies establish a voluntary register and council.

In 1936 the General Council and Register of Osteopaths (GCRO) was established. This umbrella organisation unified the BOA and the Osteopathic Association of Great Britain,

but the latter dominated the organisation and the majority of registrants were 'lay osteopaths'.

After World War II the BOA established postgraduate training at the London College of Osteopathy (later the London College of Osteopathic Medicine) but entry was restricted to medical practitioners, formalizing the distinction between medical osteopaths and lay osteopaths.

Numerous other private schools and associations have come and gone during the latter half of the 20th century. The decline in naturopathy from the 1950s onwards resulted in an increased interest in osteopathy among naturopaths. The British Naturopathic Association renamed itself the British Naturopathic and Osteopathic Association in 1961, and their college was renamed the British College of Naturopathy and Osteopathy. A schism in this college led to the establishment of the European School of Osteopathy in the 1970s and its professional association for graduates - the Society of Osteopaths.

Other registers also sprang up for those not eligible to be on the Register of Osteopaths, including osteopathic naturopaths and members of the Society of Osteopaths. The GCRO extended eligibility to members of the Society of Osteopaths and graduates of the European School of Osteopathy in 1982, and to members of the British Naturopathic and Osteopathic Association in 1988. In 1981 an attempt was made to establish a degree programme in osteopathy at the Polytechnic of Central London, but this failed because the Department for Education and Science refused to designate it as eligible for mandatory grants (Association of Community Health Councils for England and Wales, 1988).

In May 1986 a Bill was introduced to the House of Commons under the ten-minute rule. This established a body of all-party support for statutory regulation of osteopathy (King's Fund, 1991) and laid the way for the events which were to culminate in the passage of the Osteopaths Act 1993. The King's Fund Management Committee announced in the autumn of 1989 that they were establishing a Working Party to look into the issue of statutory regulation of osteopaths. The first meeting was held on 5th December 1989. There were as many as nine organisations with a registering function "all purporting to represent osteopaths" (General Osteopathic Council, 2000b, para 412): the British and European Osteopathic Association, the British Faculty of Osteopaths, the BOA, the College of Osteopaths, the General Council and Register of Osteopaths, the Guild of Osteopaths, the International Guild of Natural Medicine Practitioners, the Natural Therapeutic and Osteopathic Society, and the Osteopathic and Naturopathic Guild (King's Fund, 1991). The Chairman of the General Osteopathic Council (GOsC), Nigel Clarke, admitted "the politics of the thing were pretty appalling" (Clarke, 2005). The process generated a great

deal of tension, much of which stemmed from the interests of the privately owned schools. Divisions depended on where people had trained and which registering body they had joined. The smaller professional bodies felt threatened by the largest registering body - the General Council for Registering Osteopaths (GCRO). Clarke recounted how they would complain that “[The GCRO are] trying to tell us what osteopathy is but we don’t do it like that here” (Clarke, 2005).

The Osteopaths Bill was first introduced into the House of Lords on 17th December 1991 by Lord Walton of Detchant, a former President of the BMA, the Royal Society of Medicine, and the GMC and who subsequently chaired the House of Lords’ Select Committee Inquiry into CAM. The Bill was amended in Committee by the House of Lords and had its Second Reading on 31st January 1992. However, the election was called before the final committee stage was passed. The Bill was introduced into the House of Commons in the new session by Malcolm Moss MP as a Private Members’ Bill. It came second in the ballot of members and had its First Reading on 10th June 1992. It had its Second Reading on 15th January 1993.

The Osteopaths Bill passed through its Third Reading in the House of Commons on 7th May 1993 and has been described as the “largest Private Members’ bill ever to be brought to a successful conclusion” (Standen, 1993). It received government support and was guided through the Commons by Tom Sackville MP (Parliamentary Under Secretary for State 1990-95).

Osteopaths were perhaps the most active of the five therapies in seeking statutory regulation during the 20th century, despite the plurality of associations and registers. Medical opposition appears to have thwarted their earlier efforts, in common with the experiences of nurses and midwives as we saw in the previous section.

4.5 Discussion

As the examples of midwives, nurses, dentists and apothecaries demonstrate, the experience of statutory regulation varies between occupational groups. There are significant differences in the reasons why regulation is sought, whether regulation is opposed, how regulation is structured, and the consequences for the status of the profession. Each profession has a unique history. And yet in each case common aspects of professionalisation can be identified, such as the formation of professional associations, publishing a journal, introducing training schools and courses, and establishing accreditation bodies.

Some health care professionals such as midwives had to fight to achieve the privileges granted to doctors, often in the face of concerted opposition by the organised representatives of the medical profession. In other cases, such as nurses, the state acted in response to public and political pressure. It had to act to ensure that standards for registration were not set too high in order to preserve the interests of the hospital service and the public. Other practitioners not discussed here in detail such as physiotherapists have accepted a subordinate position to that of doctors in order that regulation would pass (Abel-Smith, 1960; White and Marmor, 1982). Dentistry developed from within the medical profession and regulation was therefore not opposed. Dentists won protection of function, and regulation continued to be closely integrated with the medical profession. The apothecaries won early concessions from the medical profession but their occupational jurisdiction was challenged on all sides. Ultimately they lost ground to doctors (general practitioners) and to pharmacists. The profession went into demise despite winning statutory regulation.

Among complementary and alternative medical practitioners there has also been repeated efforts to put Private Members' Bills before parliament. The osteopaths repeatedly tried to gain statutory regulation without success before 1993. These efforts were either thwarted by organised opposition from the medical profession or failed because of the internal disagreements among practitioners. Doctors have tried to retain their dominance over medicine and subordinate other professional groups. At the establishment of the NHS when herbalists had the opportunity to become statutorily regulated they rejected it because they would have been subordinate to doctors. Homeopathy has been practised as a specialty within medicine throughout the 20th century, and yet it has not gained anything like the independence or autonomy that dentists have. In fact, medical homeopaths are regarded as pariahs by many of their conventional medical colleagues. They have lost ground to the non-medical homeopaths whose numbers have grown during the same period. The case of apothecary is interesting because it reminds us that professions not only emerge but also disappear. There is increasing convergence in practice between physiotherapists, osteopaths and chiropractors. Competition over jurisdictional boundaries in future may result in one or more of these professions going into decline or being subsumed by another.

The following chapters will explore in more detail the dynamics of the regulatory process which have shaped the position of CAM practitioners *vis a vis* other CAM practitioner groups and existing health care professionals. First, however, we turn to the research

literature to identify analytical concepts that can be used to examine the regulatory process that has shaped the regulation of CAM practitioners at the turn of the 21st century.

5 ANALYTICAL FRAMEWORK

5.1 Introduction

This chapter sets my research questions within the body of existing knowledge. It does not present an exhaustive review of the literature, but rather tries to understand how the existing body of knowledge can inform an explanation of why regulation of CAM practitioners takes the form it does.

The literature reviewed here is mainly drawn from theoretical work and is broad in its disciplinary approach, encompassing sociology, economics and political science. Empirical papers are reviewed for the purposes of identifying the analytical approach they adopt rather than for their content and findings. Three main bodies of literature are reviewed: (i) the literature on professionalism and professionalisation, (ii) the literature on regulation, particularly the growing sub-specialty of risk regulation,¹² (iii) the political science literature on the policy process and the force of ideas in shaping policy.

Section 5.2 provides an overview of the literature on professions and professionalisation and identifies two concepts - demand theories and supply theories of professionalisation (Dingwall, 1999). Demand theories of professionalisation suggest that statutory self-regulation results from the mobilisation of practitioners. In contrast, supply theories of professionalisation explain regulation as a result of state action.

Section 5.3 reviews both economic and sociological theories which seek to explain why occupational groups try to establish professional monopolies or achieve closure. It also reviews theories which seek to explain the conflicts that arise between occupational groups when making claims to certain activities.

Section 5.4 examines a number of theories which focus on the state's interest in professions. The supply theories of professionalisation encompass a range of social theories which view professionals or professional classes as necessary to a functioning society or capitalist economy. The section also reviews economic theories which see regulation as a response to failures in the market for professional services and the regulation literature which sees regulation as the state's attempt to minimise risks to public health.

¹² During the data collection phase of the research a strong theme emerged around the concept of 'risk'. Given the frequency with which this theme was mentioned in documents and interviews risk regulation was included in the review.

Theories of the policy process and concepts of policy subsystems found in the political science literature are reviewed in Section 5.5. These theories explain policy as the outcome of interactions between members of policy subsystems. Section 5.6 reviews the political science literature which seeks to examine the role of ideas in the policy process and considers whether ideas have an independent influence on policy change.

The chapter concludes with a presentation of the analytical framework to be employed in this study.

5.2 Professions and professionalisation in the literature

The literature on the professions has been dominated by sociologists. It has been the subject of interest for a wide range of theorists and empiricists. It ranges from those with an interest in professionals' position in the division of labour in modern societies (see Parsons, 1937) to those who criticise the professionals for their role in sustaining capitalism (Poulantzas, 1975).

For much of the 20th century, writers were preoccupied with studying archetypal professions such as doctors, lawyers and clergy to understand the essential traits that characterise these occupational groups and justify their special status in the economy and society. The trait approach has been largely discredited. Trait theories are criticised for being atheoretical and ahistorical because they ignore the social and historical conditions under which occupational groups attain professional status (Saks, 1986), avoid issues of accountability and political power and are descriptive with little explanatory value, particularly of changes over time. They accept the definition of profession provided by the professional group itself and do not question the possibility that ethical codes and monopoly over knowledge may be used by the occupational group to justify their position (Haug, 1980).

With the emergence of new professions during the latter half of the 20th century, such as engineers and architects, and the growth in paraprofessionals, a more dynamic theory was sought to explain the process by which occupational groups become professions. The question of 'what is a profession?' that had preoccupied sociologists was reformulated into 'what are the circumstances in which people in an occupation attempt to turn into a profession?' The term 'professionalisation' is used to describe the process of transition from occupation to profession (Saks, 1995). Dingwall makes a distinction between 'demand theories of professionalisation', that is those that see professionalisation as a process driven by the occupational groups, and 'supply theories of professionalisation', where professions

are created because they serve a state interest (Dingwall, 1999). The professionalisation literature will be discussed in more detail using this distinction.

5.3 Demand theories of professionalisation

Demand theories of professionalisation embrace both economic theories, which argue that occupational groups seek statutory regulation in order to create a monopoly for their services and thereby extract monopoly rents (high incomes), as well as sociological theories based on Weberian ideas of social closure. Much of the empirical research has used demand theories as an interpretive framework, analysing the particular trajectory of professionalisation followed by different occupational groups. These have also been applied to the cases of CAM practitioners (see below).

5.3.1 Professionalisation and economic interests

Economists from the time of Adam Smith have criticised the organisation of professional labour markets, and in particular their impact on the functioning of a competitive market. Professional regulation is seen as the cause of market failure (creating monopolies and barriers to entry). Smith highlighted the ability of crafts to lengthen apprenticeship programs and limit the number of apprentices per master as a means of restraining free competition and ensuring higher earnings for persons in those occupations (Ardy-Dubois, Dixon et al., 2006).

Economists who consider professional regulation a cause of market failure view it as operating in the professionals' interest (Horowitz, 1980, p16). By controlling entry and exit to the market through systems of licensure they can control the supply of services, set higher prices, and thus maximise their incomes. Codes of ethics and standards of practice are also used to regulate the numbers of practitioners and the conditions under which they can participate in the market, thus raising their income (Ardy-Dubois, Dixon et al., 2006).

In systems where the state has established a role as the dominant payer for health care services the monopoly position of the medical profession has facilitated collective bargaining over remuneration and ensured continued upward pressure on physician income. In addition to bargaining power over remuneration, the profession has historically enjoyed a privileged position within a corporatist policy-making system (Klein, 1990). From this perspective professionalisation is driven by occupational groups seeking economic gains.

5.3.2 Weber and social closure

Neo-Weberians talk about social closure and the process by which an occupational group consolidates its position within the social order (usually with economic benefits for the profession). The concept of 'social closure' is used by neo-Weberians to describe the process by which "legally privileged groups [are] able to monopolise to a considerable degree social and economic opportunities" (Saks, 1986, p34). They achieve this by exclusion of other occupational groups usually through state licensure (Parkin, 1979). They "regulate market conditions in their favour...by limiting access to a restricted group of eligibles" (Saks, 1986, p176). Social closure also occurs because professionals gain control over clients (Johnson, 1972), control over the content of their work, and control over the conditions under which they practise (Freidson, 1970). The medical profession has been characterised in the sociological literature as an 'ideal type' profession with significant autonomy over its work, dominance over other occupations, as well as sovereignty in matters of policy (Frenk and Duran-Arenas, 1993).

Larson wrote about professionalisation as:

the process by which producers of special services sought to constitute and control a market for their expertise...a collective assertion of special social status and as a collective process of upward social mobility (Larson, 1977, pxcvi).

He thus linked economic gains with social gains in status. He identified different processes of professionalisation depending on the social and historical context at the time. Larson has been criticised for seeing professionalisation as unidirectional and for ignoring the content of work, internal differentiation, and interprofessional relationships (Abbott, 1988).

Following the ideas of Larson, MacDonald has argued that social closure embraces both economic closure and cultural closure: the gaining of respect and status in society. He states that "exclusion is aimed not only at the attainment and maintenance of monopoly, but also at the usurpation of the existing jurisdiction of others and at the upward social mobility of the whole group" (Macdonald, 1995, p29). Thus social mobility and economic monopoly are both important objectives pursued by professions.

Others have argued that a process of de-professionalisation has occurred towards the end of the 20th century in which the medical profession's power has been weakened. De-professionalisation is believed to result from professions losing their monopoly over knowledge, increasingly consumer-oriented patients dissatisfied with self-serving professionals (Haug, 1976) and a growth in managerialism which restricts clinical autonomy (Gray and Harrison, 2004). The growth in the popularity of CAM has been cited as a factor

which contributes to the de-professionalisation process (see for example Salter, 2002). It is also claimed that the increasing bureaucratisation and standardisation of orthodox medical practice has fuelled demand for CAM (Freidson, 2001, p212).

Neo-Weberian approaches have also been criticised for ignoring the influence of the structural and institutional context. Nor do they acknowledge that the state has an active role in responding to groups' claims and in deciding which groups to give legal backing to in the form of statutory regulation. McDonald goes further than other demand theories by recognising that the success of the professionalisation project depends on "the legislative strategies of both profession and state, as well as the skill displayed by the protagonists on either side on particular occasions" (Macdonald, 1995, p13). The role of the state in professionalisation is the main focus of supply theories of professionalisation discussed below.

5.3.3 *Jurisdictional claims*

Abbott (1988) attempts to overcome the limitations of previous work which has tended to focus on isolated cases, and instead proposes that professions make up "an interacting system, an ecology" of interdependent occupational groups (Abbott, 1988, p33). Abbott's main focus is on 'interprofessional battles' and the subsequent shifts in jurisdictional boundaries over the content of work. Abbott recognises the force of external factors as well as the subjective qualities of the task in precipitating change (Abbott, 1988, p33), but still portrays the state as the audience for professional claims (Johnson, Larkin et al., 1995).

Abbott is not alone in highlighting interprofessional conflict. Tuohy (1976) argues that technological changes precipitate 'boundary disputes' between professional groups over the redefinition of professional property rights. She predicted that in the face of democratic pressures, governments would increasingly have to intervene to ensure that decisions are informed by both specialised knowledge and lay judgement. Light (1995) argues that where dominance over a particular occupational task results in the extraction of monopoly rents 'countervailing powers' will emerge to challenge and recontest the boundaries (Light, 1995). He suggests that professional position can be won and lost. Professional dominance viewed from a longer historical time period can be seen as one era in a cycle of countervailing powers (Light, 1991, p502). Patients, health care institutions, insurers, other professions or adjacent occupations may all have countervailing power to professionalism. He argues that "the degree of dominance consists of one's ability to override, suppress, or render irrelevant challenges by other parties, either behind closed doors or in public" (Light, 1991, p505). In his study of the professions supplementary to medicine, Larkin (1983) explores

jurisdictional conflicts. He argues that the success of para-professionals in claiming control over individual skills should not be interpreted as a decline in medical imperialism because the medical profession maintained “control of the entry of rivals to the market” (Larkin, 1983, p184). Although these theories see professionalisation as a dynamic process in which there are turf wars, the outcome of the process appears to depend largely on the skill and mobilisation of the occupational group, hence inclusion here under demand theories.

Demand theories of professionalisation form the first part of the analytical framework (see below). Theory suggests that the interest of occupational groups in regulation stems from their desire for economic and social closure and to establish boundaries between their work and that of other occupational groups. Chapter 7 explores the extent to which CAM practitioners have actively sought statutory regulation.

5.4 Supply theories of professionalisation

Supply theories of professionalisation depict the creation of professional groups as serving state interests. In contrast to demand theories, they view ‘protective legislation’ as the result not of ‘professional agitation’ but rather of ‘government initiative’ (Johnson, 1972, p29). Concepts of the state differ markedly. These divergent views lie at the heart of much social and political science debate. Theories about the state’s relationship with professions reflect these differences.

5.4.1 State power and social order

Theoretically it is possible to place functionalist, Marxist and Foucauldian theories of the professions within this classification of supply theories of professionalisation. These theories claim there is ‘necessary concomitance’ between professionals and the state (Frenk and Duran-Arenas, 1993). In plain English this means that the state and professionals have shared interests.

Functionalist social theorists such as Durkheim argued that professions made an important contribution to the stability of modern industrialist society and that social differentiation was necessary for the stability of society. Professions were needed to pass on knowledge for the benefit of society. As such their role and position in society was not questioned. While functionalists provide some justification for the presence of professional groups, they do not help to explain the privileged position that some occupational groups hold in society.

Some Marxist writers have suggested that professionals are necessary to the sustainability of capitalism either by performing tasks of political repression or supervising the working

classes (Poulantzas, 1975; Navarro, 1976). Professionalisation is the process by which new occupational classes are given privileged status by the ruling classes, due to their importance in sustaining and promoting the capitalist economy. Others argue that capital interests will ultimately dominate professional interests and reduce professional practice to a series of technical tasks (the process of 'proletarianization') (Larson, 1977). 'Corporatization' encompasses the same idea, that professionals are increasingly subjected to forms of corporate control, but without the Marxist assumptions (Light and Levine, 1988).

Foucault's analyse has given greatest emphasis to the interconnectedness of the rise of the modern state and the rise of professions. According to Foucault (1984) the transformation of society from traditional-authoritarian to liberal-democratic in the 18th century required a redefinition and quantification of the population (Foucault, 1984). Foucauldian accounts suggest that the creation of professions was part of the transformation in society to the modern state, and therefore reject the duality between the state and profession depicted elsewhere (Johnson, Larkin et al., 1995).

According to these theories the state has historically permitted or facilitated the rise of professions because they contribute to social order and stability, serve capitalist interests, or play a key role in the modernisation of society. These theories of the state interest in professions are very different from theories of regulation to which we now turn.

5.4.2 Addressing market failure

The classical regulation literature is mostly economic. It has focused on the impact of regulation on the market in professional services.

There are a number of reasons why a market in professional services might fail, including a concentration of economic power, barriers to entry and exit, heterogeneous services, lack of information and externalities. Although most are not unique to professional services, it has been argued that the serious information problems and pervasive externalities might call for 'special regulatory intervention' (Wolfson, Trebilcock et al., 1980, p189). In particular professionals are often both the agent and the provider of services and therefore the relationship relies heavily on trust (see below). These market imperfections mean that consumers cannot easily compare the price and quality of professional services. The main approaches to the regulation of the providers of services are: licensure and certification. Licensure is defined as restrictions on the right to practise while certification refers to restrictions on the use of a reserved title (Wolfson, Trebilcock et al., 1980).

Others argue licensure overcomes failures in the market for professional services by only allowing providers who meet minimum quality standards to enter the market. It is preferable to other forms of regulation because it prevents the costs of incompetence arising (i.e. the damage does not have to have occurred), it provides a strong incentive for providers to comply (loss of licence is the ultimate sanction), it promotes consumer confidence (even among small firms), and stops high quality providers from exiting the market (Wolfson, Trebilcock et al., 1980, pp 206-7). Svorny (1987) presents evidence that licensure induces quality:

The ability to use the government's force to deny a physician the right to practice medicine once he or she has engaged in undesirable practices is what favors licensure over certification in the production of quality assurance (Svorny, 1987, p500).

However, licensure has been criticised for being inflexible, leading to increased demand in substitute markets, reduced access and higher prices due to entry criteria being set too high, and may be irreversible (due to the losses inflicted by revoking regulation) (Wolfson, Trebilcock et al., 1980). Given these weaknesses it has been suggested that licensure be reserved for professional markets where there are high costs of error, high consumer information costs and widespread negative third-party effects which are not able to be fully compensated (Wolfson, Trebilcock et al., 1980).

Certification, on the other hand, overcomes asymmetries of information but does not prevent non-certified practitioners from practising. There is some debate about whether certification is sufficient to ensure quality in the market for professional services.

The idea that professionals contribute to the smooth functioning of the economy are also reflected in the writings of sociologists and political scientists. Freidson (2001) claims that professionalism is the 'third logic' alongside commercialism and bureaucracy for the delivery of services (Freidson, 2001). Indeed despite the market imperfections, "society permits these self-serving practices to persist, in exchange for a guarantee of a certain minimal level of competence on the part of the professional that serves it" (Horowitz, 1980, p16). Light (1991) argues that professionalism is an alternative to either markets or hierarchies and is an efficient form of production, especially in complex situations involving uncertainties such as health care (Light, 1991). Dingwall (1999) also argues "The professional is our means of reducing uncertainty about important things that we cannot easily or economically verify for ourselves" (Dingwall, 1999, p10). In other words trust is necessary for exchange to take place. Codes of ethics and high standards of entry support this trust relationship.

Others have argued that the market in professional services is not that different from other types of services – “there is no more – and no less – trust involved in buying professional services than in buying groceries” (Lees, 1966, p33). The role of the state therefore should be to promote competition and to keep markets open for new entrants.

5.4.3 Public protection and the risk society

More recently there has been a growing interest in risk in the regulation literature.¹³ The general preoccupation with risks, particularly those to human health, has intensified at the beginning of the 21st century. Sociologist Ulrich Beck has characterised modern society as the ‘risk society’ (Beck, 1992). In his account of modernization in late industrial societies he argued that as well as producing goods and services the modern economy produces ‘risks’, for example in the form of environmental pollution or social problems. These risks are more abstract and invisible, and more difficult to quantify or control than in the past, and as a result of globalisation they transcend boundaries of class, race and nation state. Information about these risks tends to reside with experts and creates uncertainties for lay people. Science and industry are seen as both the source of information and as the producers of risk. Consequently the public seeks alternative expertise and knowledge to understand the risks that have entered their everyday lives (Tulloch and Lupton, 2003).

These unseen risks can cause social alarm, often fuelled by media reporting of risk. Whether it is the risk of developing Creutzfeldt-Jakob Disease from eating infected meat (Lanska, 1998), the risks associated with mobile phones and masts (Burgess, 2004), or the association of the measles, mumps and rubella (MMR) vaccine and autism (Hargreaves, Lewis et al., 2005) the interaction between the media and scientists has resulted in a number of public scares and panics. A number of factors (too complex for any substantive discussion here) may be to blame: publication of and publicity for low quality scientific studies, poor interpretation of scientific results by journalists, and difficulties of risk communication to the general population. Moral panics are nothing new in themselves, but governments’ responses to them are.

The regulation literature on risk has focused on the state’s response to risk in society. Traditionally risk regulation has been associated with the field of health and safety legislation, but recently has been more broadly defined as “governmental interference with market or social processes to control potential adverse consequences to health” (Hood, Rothstein et al., 2001, p1). It is claimed there has been a shift towards a precautionary

¹³ Hazard is a measure of potential harm and is concerned with (negative) impact, risk is the probability of an event or harm occurring and can be statistically measured, whereas uncertainty is the extent to which the hazard or risk is unknown.

approach to regulation,¹⁴ particularly where risks to human health and the environment are concerned. This means that risks that were previously tolerated under a ‘wait and see’ approach are now subject to regulation under a ‘just in case’ approach. This trend in government and among regulators towards risk regulation has been termed ‘new public risk management’ (Black, 2005).

Dingwall (1996) sees professional regulation as “a state project to tidy up the market for health care provision in support of its own developing stake in public health” (Dingwall, 1996, p5). Dingwall points to risk as a significant factor in the regulatory process. For example, he claims the formation of the Royal Pharmaceutical Society was not the result of the efforts of organized interests of pharmacists, but rather the state response to “moral panic about the increasingly potent organic compounds that were becoming available” (Dingwall, 1996, p5): in other words, a state response to a perceived risk to health.

Supply theories of professionalisation form the second element of the analytical framework. Theories suggest that the state’s interest in regulating CAM practitioners may stem from a desire for new professionals groups to contribute to social and economic order, to correct market failures or to reduce risk. The state’s interest in the professionalisation of CAM practitioners is explored in Chapter 8.

5.5 Policy subsystems

The third element of the analytical framework seeks to combine the ideas that underpin the demand and supply theories of professionalisation. Refinements of interest group theories acknowledge an active role for state actors, and focus on interactions between groups and among participants within groups. This study uses a novel adaptation of policy subsystem analysis – personal policy network analysis.

5.5.1 *Policy communities, issue networks and advocacy coalitions*

The assumption underlying pluralism is that power is distributed across various groups in society. Lasswell and Kaplan (1950) saw power as part of the social process and argued that policy was created dynamically and shaped by individual actors and interest groups (Lasswell and Kaplan, 1950). Early interest group analysis tended to assume a direct causal effect between interest group influence and subsequent state action. Research focused on the level of group influence (as measured by the resources available to groups), and as a consequence neglected the relationships between interest groups and diminished the role of

¹⁴ The response to uncertainty can be twofold: firstly to introduce precautionary regulation in case there is later found to be a hazard where originally none was assumed to exist (type II error) or to take a conservative approach to regulation and allow continued exposure to the hazard rather than introduce unnecessary regulation (type I error).

the state. Political parties and organized interests were simply seen as a transmission belt between the state and society (Hall, 1993). In the health policy literature such theories have been used to explain why the state has often given priority to the demands of the medical profession (Gladstone, 2000).

Policy subsystems have variously been called communities, networks and coalitions. Early concepts of these relationships depicted an 'iron triangle' between government officials, politicians and interest groups. Such a group of closely linked stakeholders with homogenous ideas and interests has been termed a 'policy community'. However, these fixed and stable relationships provide a somewhat over-simplified version of real-world policy-making. The complexity of policy-making is wonderfully captured in this description by Heclo (1974):

a maze where the outlet is shifting and the walls are being constantly repatterned; where the subject is not one individual but a group bound together; where this group disagrees not only on how to get out but on whether getting out constitutes a satisfactory solution; where, finally, there is not one but a large number of such groups which keep getting in each other's way (Heclo, 1974, p308).

Heclo (1990) identified looser associations of interested parties which he termed 'issue networks' (Heclo, 1990). The work of Heclo and others suggests that the allegiances and alliances forged between interest groups, and the strength of these, are important to explain eventual policy outcomes.

Marsh and Rhodes (1992) set out ideal types of policy communities and issue networks at either end of a spectrum, differing in membership, level of integration and resources (Marsh and Rhodes, 1992) (see Table 5.4). Smith argues that the nature of relationships within a policy subsystem will depend on the level of state autonomy. Where the government depends upon groups for implementation, particularly those with important resources to exchange, policy communities are more likely. In contrast, in areas of lesser importance to government, of high political controversy, or in new issue areas where interests have not had the time to establish institutionalised relationships, issue networks will develop (Smith, 1993).

Table 5.4 Dimensions of policy communities and issue networks

Dimension	Policy community	Issue network
Membership		
Number of participants	Very limited, some conscious exclusion	Large
Type of interest	Economic/professional	Wide range of groups
Integration		
Frequency of interaction	Frequent, high quality	Contacts fluctuate
Continuity	Membership, values, outcomes persistent	Fluctuating access
Consensus	All participants share basic values	A degree of agreement but conflict present
Resources		
Distribution of resources within network	All participants have resources. Relationship is one of exchange	Some participants have resources, but limited
Distribution of resources within participating organisations	Hierarchical leaders can deliver members	Varied and variable distribution and capacity to regulate members
Power	There is a balance among members. One group may be dominant but power is positive-sum	Unequal power. Power zero-sum

Source: (Marsh and Rhodes, 1992)

Sabatier (1988) develops these concepts further and argues that within any policy subsystem there will be a number of competing advocacy coalitions made up of “people from various organizations who share a set of normative and causal beliefs and who often act in concert” (Sabatier, 1988, p133). The advocacy coalition framework recognises that people may have a range of beliefs that are not always related to their formal role within an organisation, and who may have membership in more than one coalition.

Research in the pluralist tradition has tended to give primacy to organized interest groups and has downplayed the role of the state and the ability of state actors to act autonomously (Smith, 1993). Smith (1993) suggests the focus should also be on the interests and activities of state actors, because it is through mechanisms of inclusion and exclusion that the state creates insiders and outsiders. He argues that “Past policies, ideology and the way policy is made can advantage some groups over others” (Smith, 1993). This is in contrast to the Weberian ideal type of the bureaucrat. It is not simply a matter of politicians decide and officials ‘carry out’. Page (1992), for example, argues that civil servants are policy-makers as well as policy executors (Page, 1992, p51). These sentiments are echoed in the work of

Heclo, who recognises that “administrative actors have been crucial in giving concrete substance to new policy initiatives and in elaborating already established approaches” (Heclo, 1974, p304).

Freidson, much of whose work focuses on the medical profession, recognises the importance of the interaction between occupational groups and the state. He writes:

The foundation of medicine's control over its work is thus clearly political in character, involving the aid of the state in establishing and maintaining the professions' pre-eminence...it is by the interaction between formal agents or agencies of the occupation and officials of the state that the occupation's control over its work is established and shaped (Freidson, 1970, p23, my emphasis).

McDonald also writes in a similar vein:

professional/ state interactions are seen as the outcome of actions and reactions on the part of the officers of a professional body, their counterparts in other professional bodies and in various Civil Service departments. Crucial to that outcome are the legislative strategies of both profession and state, as well as the skill displayed by the protagonists on either side on particular occasions (Macdonald, 1995, p13).

Neither of these authors actually explore these interactions but instead focus primarily on professional activities. These interactions between the state and professions are central to the theories that seek to explain the dynamics of the policy process.

5.5.2 Individuals and the policy process

Rhodes (2002) proposes that research of policy networks has lost sight of the individuals within networks. He argues for a constructivist approach that would put people back into networks by exploring “the ways in which they are made and remade through the activities of particular individuals” (Rhodes, 2002, p400).

A number of approaches have developed which focus on individuals within policy subsystems. Each approach has very different assumptions about the role of individuals and how decisions are reached. The rational choice approach sees outcomes as the result of bargaining between agents in the network (see Dowding, 1991). The personal interaction approach emphasizes personal relationships between known and trusted individuals who share beliefs and common culture (see McPherson and Raab, 1988). The formal network analysis sees the positions and roles that actors perform and the relationships between these roles as crucial (see Laumann and Knoke, 1987).

Sabatier (1988) argues that “...institutional models have difficulty accounting for the importance of specific individuals who move about from organization to organization within the same subsystem” (Sabatier, 1988, p140). These so called ‘policy brokers’ mediate between competing advocacy coalitions in order to establish the basis for consensus.

Heclo (1974) and Kingdon (1984) have also recognised the role of (pro)active individuals who were able to seize the opportunity to achieve policy change, called ‘policy middlemen’ and ‘policy entrepreneurs’. John (2003) believes individuals also play an important role in the selection of policy ideas. He defines policy entrepreneurs as:

activists with a particular interest in the success of the policy though in a less acute sense everyone is an entrepreneur who has a stake in the policy outputs and outcomes, the citizens who vote for policies, politicians who seek to maximize votes and capitalize on policy opportunities and bureaucrats who have a stake in the implementation of particular policy choices (John, 2003, pp493-4).

The approach adopted in this study responds to the call to put people back into networks (Rhodes, 2002) and sees influence as related to connections between people. It is similar in design to Lewis (2006) in which social networks of interpersonal ties are the focus (Lewis, 2006). Unlike many analyses of policy communities, issue networks and advocacy coalitions that focus on interest groups the analysis in this study includes state actors and is at the level of individuals.

The approach called ‘personal network analysis’ is an adaptation of existing approaches and focuses on individuals. It forms the third element of the analytical framework (see below) and is applied to the regulation of CAM practitioners in Chapter 9.

5.6 Institutions and ideas

Other theories explain policy as the result of either endogenous aspects of the network or policy subsystem, or exogenous or structural factors, or both. Analysis that focuses on groups has been criticised for ignoring beliefs and structures (which could also be termed ideas and institutions). For example, Smith (1993) argues:

In analysing groups and policy-making it is inadequate to focus solely on groups. It is necessary to take an historical approach which examines the nature of the relationships that have developed in particular policy sectors. It is important to examine the mechanisms for inclusion and exclusion, the beliefs that are dominant in a policy areas and the structures of the policy process (Smith, 1993, p11).

5.6.1 *Structural factors*

Structural approaches, such as that of the historical institutionalists, argue that the institutional organisation of the polity and economy favours some groups over others (Hall and Taylor, 1997). Institutionalists emphasise the importance of organisational rules and social environments in shaping policy (Koelble, 1995). The main argument is that prior institutional choices will limit future options. As an explanatory theory it tends to favour policy stasis or path dependence over policy change.

Institutional and organisational theories have been applied to the study of regulation (Levy and Spiller, 1996) and health care policy (Immergut, 1990; Immergut, 1992; Moran and Wood, 1993; Tuohy, 1999a; Tuohy, 1999b; Tuohy, 2003). Political institutions are believed to shape the outcomes of interest group activity. As Wolfson, Trebilcock et al. (1980) observed “policymakers are rarely if ever presented with a blank slate, and the field of professional regulation is no exception” (Wolfson, Trebilcock et al., 1980, p188). Most accounts focus on historical institutionalism but there is increasing interest in cultural institutionalism, where embedded social norms and values can also shape policy outcomes. Institutions, then, may constrain the possibilities for regulation, or at least shape the design of regulation.

Institutionalist approaches are criticised for their inability to explain change. March and Olsen (1997) argue that “Institutions are usually associated with routinization and repetition, persistence and predictability rather than with political change, and flexibility, agency, creativity and discretion” (March and Olsen, 1997). While stabilisation may be appropriate in the short term if institutions are not able to respond to the changing context they may become obsolete. The structural approach downplays interpersonal relationships in favour of structural aspects (Marsh and Smith, 2000).

Exogenous factors (such as economic, ideological, political and knowledge-based factors) will be important in shaping policy networks, but the networks themselves have a role in mediating their influence. Marsh and Smith (2000) propose a dialectical approach to the study of policy networks, which recognises a two-way relationship between structure and agency, network and context, and network and outcomes (Marsh and Smith, 2000). Power relationships within the network are institutionalised by previous policy (structure), but members of a network also shape the structures within which they operate. They “choose policy options, bargain, argue and break up networks” (p7). This process of structuration needs to be incorporated into network analysis. According to Marsh and Smith (2000):

...any explanation of change must emphasize the role of agents, while also acknowledging that the broader context within which the network operates affects the interests and actions of network members (Marsh and Smith, 2000, p7).

The relationship between networks and outcomes, however, is not unidirectional. Policy outcomes shape the context within which future policy issues are considered. They may lead to changes in membership or the balance of resources within the network, affect the social structure and weaken the position of certain interests, or may affect agents through the process of strategic or policy-oriented learning (Marsh and Smith, 2000).

Sabatier and Jenkins-Smith (1999) argue that the accumulated evidence suggests that “policy beliefs shared by members of different institutions may be at least as important in explaining their behaviour as the institutional rules that apply to members of a given institution” (Sabatier and Jenkins-Smith, 1999, p130). Heclo sees policy as an outcome not only of the impact of previous policy but also as a result of the interrelationships between organisations and individual agents of change (Heclo, 1974).

5.6.2 Ideas

Ideas have been variously defined as policy proposals, new techniques or solutions, systems of ideas, or discourse and language (John, 2003). According to Heclo (1974) politics is concerned not only with power but also uncertainty, and consequently he believes “Governments not only ‘power’...they also puzzle” (Heclo, 1974). In his analysis of the development of welfare policies in Britain and Sweden he conceives of policy-making as a form of collective puzzlement on society’s behalf or a ‘process of social learning’. So the flow of ideas (and who controls them) are important to an understanding of the policy process.

The concept of social learning focuses on how policy experience and new information can shift officials’ and policymakers’ ideas. Hall (1993) describes how social learning influences the policy process:

In order to understand how social learning takes place, we also need a more complete account of the role that ideas play in the policy process. ..policymakers customarily work within a framework of ideas and standards that specifies not only the goals of policy and the kind of instruments that can be used to attain them, but also the very nature of the problems they are meant to be addressing (Hall, 1993, p279).

External actors, including researchers and the media, also influence the process of social learning (Hall, 1993).

Kingdon (1984) identified three streams (policy, politics and problem streams), the confluence of which is necessary before an issue will be addressed (Kingdon, 1984). Problems are usually identified by researchers through analysis of routine data, but may also result from a crisis or focusing event or emerge from evaluations and feedback of existing policy. Politics includes both visible and hidden participants. The politics stream is largely driven by the salience of political events and the ideologies of parties in power. Academics and the media are the hidden participants who may generate attention for a particular problem or put forward available policy alternatives. Working in the policy stream are the civil servants who will decide whether to pluck an idea from the 'primeval soup'. So the identification of problems and policy solutions and the decision to act result from the complex interplay of academics, the media, politicians and civil servants.

Sabatier (1988) argues that policy changes result from changes in the dominant beliefs within a policy subsystem. Policy change occurs as elites from different advocacy coalitions "gradually alter their belief systems over time, partially as a result of formal policy analyses and trial and error learning" (Sabatier, 1988, p130). He suggests that "there will be greater fragmentation of beliefs in recently-formed subsystems than in more established ones" (Sabatier, 1988, p140).

Baumgartner and Jones (1991) argue that opportunities for policy change open up when an issue is redefined or there are shifts in institutional control.¹⁵ They argue that:

Issue definition is the driving force in both stability and instability, primarily because issue definition has the potential for mobilizing the previously disinterested. The structure of political institutions offers more or fewer arenas for raising new issues or redefining old ones – opportunities to change understandings of political conflict. Issue definition and institutional control combine to make possible the alternation between stability and rapid change that characterizes political systems (Baumgartner and Jones, 1991, p16).

By focusing on changes in ideas and institutions ('policy images' and 'policy venues' in their terminology) they can explain both stability and change within a pluralist perspective (Baumgartner and Jones, 1991). Elaborating on these ideas, Baumgartner and Jones (2002) argue policy change depends on whether new ideas are reinforced with positive feedback or countered with negative feedback. Negative feedback will bring the system back into equilibrium, whereas positive feedback will amplify the issue and result in policy change (Baumgartner and Jones, 2002). They suggest that positive feedback can accentuate a policy trend through cue taking or mimicking by policy actors (the idea of a policy bandwagon or

¹⁵ The idea of punctuated equilibrium was borrowed from evolutionary theory to explain periods of volatile change.

policy fads and fashions), or as a result of a shift in attention (due to cognitive limitations and serial information processing only one aspect of an issue may be in focus at any one time).

The spread of policy ideas between countries or between sectors has been likened to a virus and may challenge existing policy communities and networks. “New ideas have a virus-like quality and have an ability to disrupt existing policy systems, power relationships and policies” (Richardson, 2000, p1021). The survival of a policy network, as in evolutionary theory, will depend on the extent to which it can adapt itself or mutate the idea (John, 2003).

Hall (1993) contrasts periods of ‘normal policymaking’ with third order changes which result in a shift in the policy paradigm (drawing on Kuhn’s idea of paradigm shift in scientific research) (Hall, 1993). Hall cites several factors that might precipitate such a radical shift:

accumulation of anomalies, experimentation with new forms of policy and policy failures that precipitate a shift in the locus of authority over policy and initiate a wider contest between competing paradigms (Hall, 1993, p280).

In the regulation literature some writers assert that the ‘force of ideas’ may in itself be sufficient to shape regulation (see for example Hood, 1994). The force of ideas in steering regulatory developments has not been extensively tested on empirical examples but it is likely that these factors interact, for example with particular interest groups pushing certain ideas (Baldwin and Cave, 1999, p19).

In a comparative assessment of a number of risk regimes Hood, Rothstein et al. (2001) propose three hypotheses to explain risk regulation regimes: market failure pressures, opinion responsive government, and interest driven pressures. They also suggest that ideas, policy entrepreneurship, and internal processes of institutions (including formal rules, the interests of technocrats, bureaucrats and professionals operating within state institutions and the culture of institutions) will have a role in shaping regulatory regimes (Hood, Rothstein et al., 2001). They conclude that regulation is the product of the dynamics of the policy process in which public opinion and attitude to risk play an important role.

The concepts examined here about the role of ideas and institutions in shaping policy form the final element of the analytical framework. Chapter 10 applies this to the research question; why was a particular model of regulation adopted for CAM practitioners.

5.7 Empirical research

The empirical underpinnings of demand theories of professionalisation are weak. Most studies have taken single cases and told a narrative story about an occupation's transition from occupational group to profession. For each case attempts are made to generalise and find a series of common steps which might be followed by an occupation in transition. Little attempt is made to explain how and why this process occurs. The steps and the particular order have varied between studies but usually include: shift from amateur to professional or specialisation of work, establishment of training schools (followed by an attachment to a university), development of a professional association, public recognition and legal support, and finally a code of ethics (Johnson, 1972). This approach assumes that there is some evolutionary linear process which all occupational groups will follow (Wilensky, 1964) and has been roundly criticised. Firstly because comparative analysis has shown that cases vary in the order these steps are achieved, secondly because some occupations are not granted professional status despite completing these steps, and thirdly because some occupational groups lose as well as gain professional status (Abbott, 1988). Most researchers would agree with Johnson (1972) that "there is no uniform or unilineal process of professionalisation which is of universal applicability" (Johnson, 1972).

Baer (1981, 1984) followed the trait approach by looking at professionalisation as an evolutionary process. In his analysis of the professionalisation of osteopathy in the UK, Baer (1984) acknowledges that although steps such as establishing a voluntary register are necessary they are not sufficient conditions for state regulation. Ultimately political and economic elites had to be convinced of a need for osteopathy to counter the "contradictions of capital-intensive, high technology medicine" (Baer, 1984). A similar approach is adopted in the analysis of professionalisation of acupuncture in the San Francisco Bay area. The creation of schools of traditional Chinese medicine (TCM) and acupressure are seen as important steps in the process, as well as changes in the knowledge base to incorporate biomedical explanations (Baer, Jen et al., 1998).

Clarke, Doel et al. (2004) analyse the process of professionalisation among CAM practitioners in the UK using documentary evidence (Clarke, Doel et al., 2004). They identify how the costs and benefits of statutory regulation are portrayed in documents circulated by nine national associations to their members (representing aromatherapy, Chinese herbal medicine, chiropractic, crystal healing, feng shui, lay homeopathy, medical homeopathy, osteopathy and radionics). This work links to demand theories of professionalisation by assuming that regulation is pursued by the professions (who make rational decisions about whether to lobby for regulation).

Theories of social closure have formed the basis for much work on the regulation of CAM practitioners. Most of Saks' work has adopted this theoretical approach including his work on acupuncture in the UK (Saks, 1986). Research among medical and non-medical homeopaths in the UK also drew heavily on theories of social closure. Cant and Sharma (1996) aimed to identify the strategies employed to demarcate homeopathic knowledge from other potential providers (Cant and Sharma, 1996).

The concept of 'jurisdictional boundaries', put forward by Abbott (1988), has been applied empirically in a number of studies. For example, Norris (2001) drew on Abbott's ideas that professionals form an interlocking system in which they compete for work. The analysis focused on how different occupational groups involved in the treatment of musculoskeletal problems in New Zealand express and produce differences between occupations in order to maintain boundaries (Norris, 2001). There has been a delay between the publication of theoretical work on the professions and its use in informing empirical studies of the professionalisation of CAM practitioners.

Fournier (2002) explores how the identity of a professional aromatherapy practitioner was created in opposition to ideas of the naïve amateur and the unscrupulous quack (Fournier, 2002). This draws on theories of social construction. Although it does not mention Abbott specifically, it does explore how aromatherapists set jurisdictional boundaries within an area of practice that is also occupied by beauty aromatherapists and the lay public.

Three connected studies conducted in Ontario, Canada have combined social closure theories with the ideas of jurisdictional boundaries. Boon, Welsh et al. (2003) conducted focus groups with naturopathic practitioners, homeopaths and TCM/acupuncture practitioners in order to explore the "micro-level dimensions of professionalisation" (Boon, Welsh et al., 2003). This study, like others focusing solely on the occupational groups seeking regulation, did not attempt to understand the relationship between CAM practitioner groups and state actors or other stakeholders.

The second study aimed to identify the strategies employed by leaders of professional associations to pursue the goal of statutory regulation (Welsh, Kelner et al., 2004a). The focus was on the internal battles, rather than the relationship with external groups such as doctors and government, and looked at how knowledge claims were used to set boundaries between good and bad practitioners and to signal externally that practitioners are qualified and legitimate. The authors recognised that external factors, such as the actions of other health care groups, and the readiness of government to respond to requests for self-regulation exert an influence on policy.

In the final study Kelner, Wellman et al. (2004) conducted a series of interviews with government officials in Ontario involved in the policy to regulate CAM practitioners. They sought views on the role of the state in the professionalisation of CAM practitioners, as well as their attitudes towards further integration of CAM in the public health system (Kelner, Wellman et al., 2004b). The approach was still largely based on ideas of social closure. Their interest in state actors was to understand why CAM practitioners had been “hampered in their efforts to achieve legitimacy by the general absence of state support” (Kelner, Wellman et al., 2004b, p81). The authors explicitly recognize a tension inherent in the objectives of the state (to rationalize health care and get value for money, respond to public demands for greater choice of modalities and to protect the public from harm). These are described as constraints on the state’s ability to act, as is the influence of established health care professionals (especially doctors). They do not analyse the interplay of these different interests.

5.8 Analytical framework

The analytical framework consists of four elements: demand theories of professionalisation (A), supply theories of professionalisation (B), personal network analysis (C), and ideas (not shown) (see Figure 2.3). Chapters 7-10 use this framework to examine the regulatory process in relation to the cases of acupuncturists, chiropractors, herbalists, homeopaths and osteopaths.

Common to the demand theories of professionalisation is the idea that statutory regulation results from the claims and activities of occupational groups. From this perspective one would expect to find that CAM practitioner groups who are statutorily regulated have actively pursued regulation in order to obtain economic and social benefits. Chapter 7 tests the explanatory value of demand theories of professionalisation. The chapter examines whether the policy process has been dominated by practitioners interested in achieving social closure.

Supply theories of professionalisation claim that statutory regulation is the result of government initiative rather than the activities of occupational groups. From this perspective one would expect to find that the state has introduced regulation of CAM practitioners to meet its own ends. Chapter 8 tests the explanatory value of supply theories of professionalisation.

Personal network analysis is the name given here to an approach which analyses the positions and roles of actors who are engaged in the policy process and also the

interrelationships between these individuals. This approach is justified by the characteristics of the CAM policy subsystem observed during the initial phase of data collection:

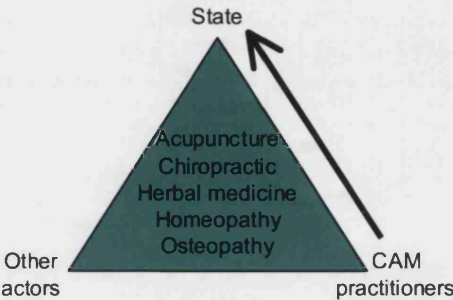
- CAM interest groups are at a formative stage and relationships are less institutionalised than among actors in the wider health policy community.
- Many people promoting the statutory regulation of CAM practitioners simultaneously hold positions in several organisations.
- There are fewer full-time representatives of CAM practitioners than one finds among other health care professionals.

This approach assumes that statutory regulation of CAM practitioners is the outcome of actions by and interactions between individuals within the policy subsystem. Chapter 9 tests the explanatory value of personal network analysis.

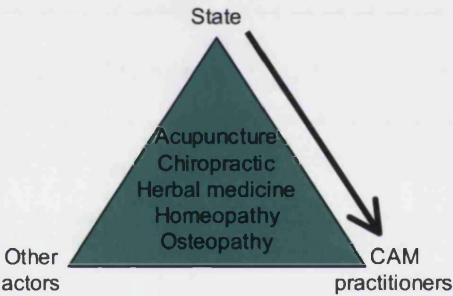
Finally, Chapter 10 examines the question of how CAM practitioners are regulated. It analyses debates about models of regulation within the policy community to identify which ideas dominated. Theories about the role of ideas in the formation of policy are used to explain why alternative ideas have failed to penetrate the policy network. Before presenting the results of the analysis the next chapter sets out the methods employed.

Figure 2.3 Analytical framework

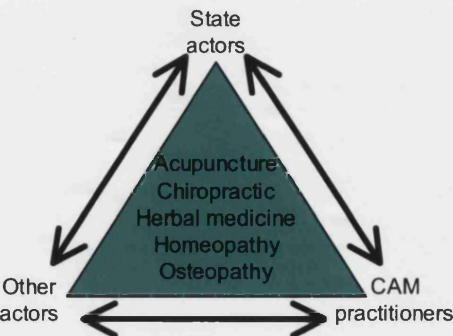
A. Demand theories of professionalisation



B. Supply theories of professionalisation



C. Personal network analysis



6 METHODS

“Good policy analysis...takes time and painstaking immersion in the details and history of the policy process” (Hood, Rothstein et al., 2001, p184)

6.1 Introduction

Among contemporary social policy researchers both quantitative and qualitative research methods are widely utilised. Past debates were preoccupied with which approach was more objective or rigorous, more valid or reliable. Today acceptance of the place of qualitative research in health services research is more widespread (though by no means universal) (Dingwall, Murphy et al., 1998), and the focus has shifted on to how to ensure or judge high quality qualitative research (Giacomini and Cook, 2000). It is not the purpose of this chapter to revisit epistemological debates about the philosophy and methods of the social sciences, but rather to provide information to enable the research design and process to be traced (and therefore critiqued).

The chapter presents descriptions of (i) the research design and (ii) the analytical process. It is hoped that the chapter will provide sufficient information about the collection and selection of data to allow the validity of the research to be judged, and provide enough about the analytical process to allow the reliability of the research to be judged.

No research, whether based on numeric data or qualitative data, is fully objective. The prior experiences and knowledge, interests, and values of the researcher play a large part in guiding the selection of the initial research questions and the themes or statistical relationships that are identified as interesting and worthy of further, deeper investigation. The chapter therefore begins with an outline of my own interests, assumptions and prejudices.

6.2 Researcher assumptions

Knowledge is essentially based upon a value framework that is held by the researcher and shaped by the context in which they operate. It is likely that people's constructed realities are shaped by the dominant views at any particular time or place. Following the work of Kuhn, who documented the effect of powerful preconceived ideas on the work of the scientific community (Kuhn, 1970), the study assumes epistemological subjectivity. In line with Kuhn, I assert that the researcher's own assumptions are shaped by the wider dominant social paradigm.

Although I have not set up the research setting as I would in experimental research, as the sole investigator I have devised and conducted the interviews, selected the documents for analysis and coded the data without a second co-researcher, and therefore my personal value framework has had an important role in the design, data collection and analysis. Consequently I have striven to remain sensitive and open during data collection in order to relate to the meanings and perspective of the subjects (as they see it). The perspectives of supervisors and advisers have been vital throughout the process to enable me to critically reflect on the research design and data, corroborate relevant themes to pursue, and identify supplementary themes worthy of exploration that might otherwise have been overlooked. I have also tried to remain reflexive at all stages of the research, for example cognisant of my effect on the subjects during data collection, and explicit about my reactions during data analysis.

One concern for interviewees was whether I had a particular interest or bias in relation to complementary and alternative medicine (CAM). My answer was that I was neutral. I come from a family of medical practitioners, to whom I am grateful for fuelling my interest in health policy, so am grounded in a conventional medical background. The social paradigm, in the United Kingdom at least, remains dominated by biomedicine and this has the tendency to promote general scepticism of CAM therapies. However, through close personal friends, rather than personal experience, I have seen the beneficial effects of seeking assistance from acupuncturists, chiropractors and osteopaths, herbalists, spiritual healers and aromatherapy masseurs. I am therefore open to the possibility that CAM can contribute to healing and well-being. However, my concern here was not with normative questions of whether CAM does or does not work, whether it should or should not be funded and available on the NHS, nor if it should or should not be regulated. Thus any views on these issues should not have overly influenced my approach to understanding how we got to the position we are in today in relation to the regulation of these practitioners.

As a result of the research process my own views on whether and how complementary medical practitioners should be regulated have crystallized. (These are discussed briefly in the conclusions). My own ideas about regulatory approaches were shared with one or two interviewees, in an effort to establish whether alternative strategies had been considered or debated previously and to gauge reactions. Informally through my own contact with policymakers and formally through interviews and supervisions it is possible that my ideas have seeped into the policy process. My own views on the regulation of CAM practitioners

have been further influenced by the research I have undertaken and these are discussed in the concluding chapter.

6.3 Justifying the methodological approach

The increasingly multi-disciplinary nature of social policy research is opening up the methodological Pandora's box, with historians, political scientists and anthropologists joining economists and sociologists. It presents exciting opportunities for new research questions to be answered and for new perspectives on old questions. Political scientists are often more interested in why things happen the way they do, in the process of policy. Traditionally social policy research focused on policy content and policy outcomes. The era of public administration was dominated by evaluations of government programmes. Such research often made use of official statistics or other official data generated by public institutions (such as hospital episode statistics from the National Health Service). Research has changed as the state's role has shifted from direct provision to contracting out across a number of areas of social policy. Value for money audits and studies of performance using measures such as consumer satisfaction, financial performance and quality indicators are increasingly common.

This study focuses on process rather than on outcomes or the impact of policy. It aims to explain why regulation of CAM practitioners has taken the form that it has in the UK. It specifically seeks to identify the factors which contributed to the decision to enact legislation to regulate CAM practitioners, and to explain why certain therapies are regulated. It also focuses on policy content. It seeks to explain why the particular model of regulation has been adopted.

In order to answer these questions it is essential to get at the narrative behind the policy process, to understand what happened during this period from the perspective of those involved, and to analyse their views, opinions and actions. It requires 'immersion' in the policy debates that took place in order to identify ideas that were held and influences that held sway. The study therefore utilises qualitative research methods.

This methodological approach is particularly well suited to the research questions addressed in this study because:

- Depicting process requires detailed description of how people engage with each other;
- The experience of process typically varies for different people so their experiences need to be captured in their own words;

- Process is fluid and dynamic;
- Participants' perceptions are a key process consideration.

In common with other qualitative research this study assumes that there is no single absolute reality but that there are multiple realities (known as ontological relativity). Adopting a constructivist approach, the study attempts to construct reality on the basis of data provided by the subjects. In analysing the development of policy from multiple perspectives the intention is to reconstruct the regulatory process. In the analysis of decision-makers this constructed reality has been termed an 'appreciative system'. Vickers (1965) defines it thus:

appreciative judgments reflect the view currently held by those who make them of their interests and responsibilities, views largely implicit and unconscious which none the less condition what events and relations they will regard as relevant or possibly relevant to them, and whether they will regard these as welcome or unwelcome, important or unimportant, demanding or not demanding action or concern by them (Vickers, 1965, p67).

This appreciative system or assumptive world informs how decision-makers process and interpret information and interactions.

Qualitative research methods seem justified in exploring an area of policymaking that has received little or no attention. The intention is not to prove or disprove well-defined hypothesis, but rather to reveal insights into the policy process which might have a wider resonance for health policy research and to explore ideas about professional regulation. Qualitative data can therefore provide the basis for re-constructing the regulatory process.

A major criticism of qualitative research is that it is more challenging to demonstrate the reliability and validity of the findings due to the active role of the researcher. A number of criteria have been suggested to assist in judging the quality of qualitative research (Giacomini and Cook, 2000). Similar guidelines and suggestions of questions to consider have been put forward elsewhere (Mays and Pope, 2000). The 'checklist' approach has been criticised for being overly prescriptive and for suggesting that following a series of technical procedures confers rigour (Barbour, 2001). While these suggest a number of ways to increase the reliability and validity of findings, ultimately the quality of qualitative research is highly dependent on the "skill, vision and integrity of the researcher" (Mays and Pope, 2000, p116).

One suggestion is to have explicit hypotheses *a priori*. However, well-defined hypotheses might suggest that other methods would have been more appropriate. In reality most

research questions are shaped and refined throughout the research process, and the design is adapted as the study proceeds. A second suggestion is to have explicit analytical constructs (or codes) prior to the commencement of analysis (Miles and Huberman, 1994). Again if these are too restrictive the researcher may overlook important issues which emerge from the data.

Proponents of grounded theory propose that researchers should use inductive methods to identify the themes that emerge from the data (Glaser and Strauss, 1968). Analytic induction proposes a number of components for the research process: constant comparison, deviant case analysis, and theoretical sampling (Dingwall, Murphy et al., 1998). At its extreme the grounded approach, in common with positivists, denies that the researcher has prior experiences and assumptions. In this study where I have been the sole person conducting both the data collection and analysis it was not feasible to maintain complete distance from the data before the commencement of the analysis. In fact most research is an iterative process of deduction and induction; a “search for regularities and cumulation” (Dingwall, Murphy et al., 1998).

In this study, theory has both informed and been informed by data analysis. (See the previous chapter for a description of the development of the analytical framework.) A number of issues and themes were identified *a priori* as being of interest, for example what did stakeholders say about the purpose of regulation, the options for regulation, and the structures of regulatory bodies. Others such as professional fragmentation, ideas about risk and public protection and the heterogeneity of practice were issues that rapidly emerged as key themes from initial reading of the data. These were incorporated and reflected in the analytical framework and codes used. The review of the literature which informed the analytical framework helped to establish a set of explanatory theories to be tested, i.e. demand theories and supply theories of professionalisation. These were used to structure the analytical codes and provided themes around which data analysis was organised.

6.4 Research design

The research uses multiple sources of data (documentary and interview) from multiple stakeholders involved in the policy process. It focuses on five complementary therapies (acupuncture, chiropractic, herbal medicine, homeopathy and herbal medicine) in order to examine the commonality and differences across groups and over time.

6.4.1 *Selection of cases*

The cases examined in this study were chosen in order to represent therapies that are used and practised extensively in the UK and the subject of policy discussions about regulation.

There are many therapies practised in the UK that are broadly classified as CAM. The House of Lords' Report identified acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy as the so-called 'Big 5' because of their widespread use (House of Lords Select Committee on Science and Technology, 2000a, p 17). As we saw in Chapter 2 this is broadly in line with the findings of population surveys. Consultations with herbalists are generally fewer than with other practitioners, but use of herbal medicines is high and growing.

Osteopathy and chiropractic were included as examples where statutory recognition is in place. Acupuncture and herbal medicine serve as examples where statutory regulation has been proposed but which currently have established systems of unified voluntary self-regulation. Homeopathy is one of several CAM therapies which has multiple registering bodies but is working towards a unified system of voluntary self-regulation. I originally envisaged that aromatherapy would be included but it soon became evident that disputes peculiar to the Aromatherapy Regulatory Working Group meant access would be difficult. It was therefore excluded.

Having selected the cases the next step was to collect data. Two main sources were used, documentary evidence and semi structured interviews.

6.4.2 *Documentary data*

The main sources of documentary data were:

- Written and oral evidence to the House of Lords' Science & Technology Sub-Committee on Complementary and Alternative Medicine published in two volumes (House of Lords Select Committee on Science and Technology, 2000b; 2000c)
- The House of Lords' Science & Technology Sub-Committee on Complementary and Alternative Medicine Report (House of Lords Select Committee on Science and Technology, 2000a),
- Department of Health proposals on the statutory regulation of herbal medicine and acupuncture (Department of Health, 2004a)

- Submissions to the Department of Health consultation on statutory regulation of acupuncturists and herbalists and the published consultation responses (Department of Health, 2005b),
- Reports of regulatory working groups for osteopathy, chiropractic, acupuncture and herbal medicine and proposals produced by the Council for Organisations Registering Homeopaths (King's Fund, 1991; King's Fund, 1993; Acupuncture Regulatory Working Group, 2003; Herbal Medicine Regulatory Working Group, 2003; Council of Organisations Registering Homeopaths, 2005),
- Hansard reports of debates on the Osteopaths Bill and Chiropractors Bill in the House of Commons and on the Sub-Committee Report on CAM in the Lords,
- Reports and publications by the Foundation for Integrated Health.

The process of document identification was iterative. As new members of the policy network were identified (see below) associated documentation was added to the data set. Documents were also suggested by or provided by interviewees for inclusion. The websites of the main CAM practitioner groups associated with the therapies of interest were searched in order to identify newsletters, press releases, publications and statements relating to their activities on regulation. A watchful eye was kept on the media and journals for articles and letters published by members of the policy network. Finally summaries of speeches made by members of the policy network at conferences and seminars organised by the Foundation were included.

A challenge of contemporary policy research is that the policy process often continues after the commencement of the research study. That was the case here. Originally the Department expected to consult on a draft section 60 Order to regulate acupuncture and herbal medicine in autumn/winter 2005 (Department of Health, 2005a). At the time of publication, there is still no indication of when or even whether the regulation will be introduced. The dilemma for researchers in such circumstances is that while it is important to include emerging data (in the form of newly published documents), a decision has to be taken as some point to stop adding data. Documents were added until June 2006 with the publication of proposals for the voluntary regulation of CAM practitioners by the Foundation for Integrated Health (Jack, 2006). A full list of documents included in the data set is included at Appendix 2. This was also necessary to ensure internal coding reliability by allowing identical searches of key words on all documents. We will return to issues of coding when I describe the analytical process below.

6.4.3 *Semi-structured interviews*

The documentary evidence was complemented by a series of 19 semi-structured interviews with key participants in the policy process.

Sampling strategy

The study used snowball sampling to identify relevant individuals. This approach of snowball or chain sampling was used by Peters and Waterman in their research of high performing companies (Peters and Waterman Jr, 1982), and is particularly suited to locating key informants. I was interested in identifying key individuals who had been actively engaged in the policy process. I therefore began by interviewing the civil servant at the Department of Health with responsibility for CAM policy.

During the interview he mentioned 24 individuals and a further nine organisations involved in policy discussions concerning the regulation of CAM practitioners. He emphasised the centrality of the Foundation for Integrated Health, so interviews were set up with the Chief Executive and the Head of the Regulation Programme. Approaches were made in autumn 2004 to a further eight interviewees. Seven responded and interviews were arranged before the end of the year. All interviewees were asked to name up to three of the most important people involved in the development of professional regulation for CAM practitioners who they thought I should speak to. Through this process the perceptions of interviewees were used to verify the selection of key informants.

A further 18 people were approached early in 2005. These were people who were mentioned by at least two of those already interviewed. Of these, nine interviews were actually conducted. Eight people did not reply despite a further attempt to contact them, and one who replied initially was not available for interview due to travel in India and did not respond to emailed questions. One of those who did not reply was able to meet at a later date and verified the findings of my analysis based on other sources. This suggests that analysis of the documentary data was probably sufficient to construct an accurate view of other people's ideas, role and position within the policy network. The non-responders were from a range of stakeholders including two academics, two parliamentarians, one civil servant and three from practitioner groups. There was therefore unlikely to be a systematic bias in the sample of interviewees. A full list of interviewees and dates are included in Appendix 3. It should be noted that no Ministers were identified through this process. This is surprising given their authority in most areas of health policy and may simply reflect the low priority of CAM as a policy issue on ministerial agendas.

Interviews

A preliminary interview schedule was developed in spring 2004. Prior to the first interview in summer 2004 the interview schedule was tailored to reflect refinements to the analytical framework and the interviewee's position at the Department of Health. It specifically included questions about the level of political interest and civil servant activity, identification of influential stakeholders (so-called 'movers and shakers'), and any opposition to regulation. Subsequent interviews were based on key topics including the reasons and justification for regulation, how regulation should operate and weaknesses with the current approach, and who interviewees' 'allies' and 'enemies' were. Specific interview questions were developed for each interviewee based around these topics, but tailored to reflect the individual's position (all interview schedules are available on request, a sample is included in Appendix 4).

Interviews were digitally recorded and were supplemented with note-taking to capture the timing of particularly important points and key phrases. Due to the opportunistic timing of one of the interviews and the location of another, recording was not feasible. Extensive notes were taken and immediately written up. After each interview the recording was checked, the interview process critically reviewed and the interview schedule amended. The interviews were semi-structured: if issues came up in a different order this line of questioning was pursued before returning to other questions on the schedule. The interview style was conversational in order to promote openness from the interviewees. Further prompts were used to clarify understanding of specific details and to ensure full responses to the questions.

Ethics and consent

At the time the research proposal was developed it was not necessary to gain research ethics approval from the university. A Research Ethics Policy which included research students was introduced at the university in December 2006. However, given the nature of the research it is likely that completion of the research ethics checklist would not have resulted in the proposal being considered by the Research Ethics Committee. The nature of the research was explained to all interviewees in writing with the invitation to be interviewed. Approaches were made by letter or email and included an abstract of the proposed research and a copy of my CV for information. Agreement to be interviewed was voluntary. At the start of each interview the nature of the research was again explained. It was made clear that confidentiality would be respected in the use and storage of data. It was also explained to interviewees that the intention was to use attributed quotes in the final analysis. Where interviewees requested that parts of the interview were off the record

this was noted in the transcripts and these portions were not included in the research. An undertaking was made that all quotes and attributed comments would be checked with the interviewee prior to publication. Verbal consent was obtained from participants on this basis. Interviews were recorded and fully transcribed. Direct attributable quotes were checked with interviewees via email before submission of the thesis. In most cases the amendments made at this stage were clarifications or re-phrasings. Only one interviewee asked for one quote to be paraphrased and remain unattributed.

Anonymity is challenging in studies of the policy process. Firstly, very often key individuals are identifiable because of their formal position (i.e. President of the GMC), particularly where both documentary and interview data are used together. Preserving anonymity for things that are said during interviews is more difficult when they are presented alongside attributable quotes from the documentary data (such as the published oral evidence to the House of Lords). Secondly, personal network analysis focuses on individuals. While the analysis does not require the naming of interviewees, information on their position would in most cases make identification by the reader very straightforward and therefore make a mockery of any claims to anonymity. For these reasons it was important that individuals who were interviewed were willing to be named in the thesis. On the other hand, it is possible that interviewees were less candid because of this.

6.5 Data analysis

There were four main stages to the data analysis. An initial analysis of the data was undertaken to identify key themes. A second more in-depth and structured analysis was undertaken to index and code the data. Thirdly all codes were checked for internal consistency and recoded if necessary. Finally phrases and quotations were selected that most accurately illustrated the views of particular stakeholders for inclusion in the write up. The software programme QSR NIVO (Version 2.0) was used to organise and code the data. This had a number of advantages over more traditional methods of coding which are discussed below. Documents available electronically and transcripts were imported directly into NVIVO. For data not available in electronic format a 'proxy' file was created in NVIVO (these are indicated by an asterisk in Appendix 2).

Analysis of documentary data began prior to the interviews in order to identify key themes on which to base the interview topic guide. During this first phase a preliminary reading of the House of Lords' Report was undertaken to generate a draft list of codes. These were then used to hand code the oral evidence for key stakeholders. Further codes were generated. Documents and transcripts were coded electronically using this initial structure,

which had emerged from analysis of the House of Lords' evidence. Further codes were created for new themes or sub themes that continued to emerge.

During 2005 the emergent coding structure was rationalised and reorganised into themes: process, risks, ideas, and professional identity. Professional identity later became subsumed under a broader code of demand theories and risks under supply theories. These codes closely reflect the theoretical concepts that emerged from the review of the literature and lie at the heart of the analytical framework. A final list of codes was thus generated (see Appendix 5 for a full list of codes).

In the second phase all interviews were re-analysed and re-coded. Documents were searched electronically by keywords and relevant paragraphs coded. Documents that were only available in hard copy, including the oral and written evidence of the House of Lords' Select Committee, were also re-analysed. Selected extracts were typed directly into NVIVO to allow these data to be searched and analysed together with the other electronic sources.

The third stage involved checking the internal consistency of the codes. This involved reading the content of the codes and checking that they matched the definitions. Some text was recoded at this stage.

The three lenses of the analytical framework were used to guide the final stage of analysis. Firstly, data relating to CAM practitioners were analysed. In particular, codes relating to whether statutory regulation had been actively pursued, the benefits and disadvantages of regulation, and whether views were divided among practitioners were scrutinised. Each of the codes was analysed separately for each therapy. Secondly, data relating to state actors, including civil servants, politicians, members of the House of Lords, and Ministers were analysed. Codes relating to the strategies employed by the state in relation to the professionalisation of CAM practitioners and the justifications for action were analysed. Finally data relating to individuals within the policy network were analysed. Each individual case was analysed to build up a picture of their role in the policy network, their affiliations and relationships with others in the network. Different phases of the policy process were analysed in this way, and differences by therapy were also examined. The final piece of analysis was focused on codes under the umbrella code 'ideas'. The main regulatory issues and preoccupations were identified, and these codes then analysed in more detail by stakeholder (CAM practitioners, the state, orthodox medicine, academics and consumer organisations). This also highlighted regulatory issues that were surprisingly not discussed by many stakeholders.

The use of qualitative software had a number of benefits. Firstly, it provided an efficient means of managing the data, which consisted of some 306 data files (17 of which were minutes of aromatherapy consortia meetings and were excluded from the set of working files). Memo files were used to record the analytical process, emerging ideas and background information on stakeholders and interviewees.

Secondly, during the coding phase electronic management of data enabled searches by key words (where the full text was available electronically). This was used for example to search for 'accreditation' and its derivatives when constructing the code relating to the accreditation of courses. However this method must be deployed cautiously. The search described also picked up an alternative meaning of the term: the prior accreditation of learning for applicants to a register.

Thirdly, during the analytical phase the use of Boolean searches was invaluable. Files were organised into sets and document attributes assigned according to document type (see Table 6.5) and stakeholder type (see Table 6.6). This information was used together with codes to retrieve a subset of relevant data for analysis. For example, a search of the union of 'Shared Council' AND 'Acupuncture' retrieves everything that was written or said about the idea of an umbrella or joint council by organisations or individuals representing the acupuncture profession. Initial investment of time to input and code the data electronically paid off in the final phase of analysis, when pinpointing and retrieval of data was made easier.

Finally, electronic management allows numeric data on the number of times an issue was mentioned to be generated. This facility has not been used in this study as the data was not drawn from a representative sample. Such information was useful in identifying key preoccupations among different stakeholders, and guided the analytical process in this respect.

Throughout the analytical process my own 'hunches' and insights have no doubt led me to focus on certain themes in greater detail. However, the three lenses of the analytical framework provided a clear structure to guide the analytical process. The results of the analysis are presented in the following four chapters. The next chapter presents the findings of the analysis using demand theories of professionalisation. It tries to reconstruct the policy process that led osteopathy and chiropractic to be statutorily regulated in the early 1990s, and led to the more recent decision to regulate acupuncture and herbal medicine. It examines whether the role played by CAM practitioners can explain the regulatory process and its outcomes.

Table 6.5 **Number of data files in working set by stakeholder type**

Stakeholder type	Totals
Acupuncture	17
Aromatherapy	0
Orthodox	37
Consumer	24
Herbal	23
Chiropractic	7
CAM	8
State	46
Homeopathy	19
Osteopathy	10
Commercial	2
Academic	12
Foundation	33
NHS	6
POW	28
NA	16
TOTAL	288

NA=not applicable

Table 6.6 **Number of data files in working set by document type**

Document type	Totals
Published document	35
House of Lords	87
Consultation response	18
Speech	28
Memo	31
Hansard	12
Email	7
Interview	22
Minutes	0
Web	13
Media	35
TOTAL	288

7 THE DEMAND FOR PROFESSIONAL REGULATION

7.1 Introduction

Demand theories of professionalisation have been used in a number of empirical studies to analyse the process by which CAM practitioners have sought to professionalise (see Chapter 5). In this chapter I test the value of these theories in explaining why some CAM practitioner groups are statutorily regulated. I examine the experience of five CAM practitioner groups: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy. The research draws on documentary data and in-depth interviews with key actors (see Chapter 6 for more details of the methodology). The primary focus of this chapter is on the professional organisations which represent CAM practitioners.

The sociological literature on professionalisation identifies a series of steps or stages that occupational groups pass through before obtaining statutory regulation. These include the establishment of professional organisations, university-based higher education courses, accreditation procedures for training courses, voluntary registering bodies, and a code of ethics. Earlier empirical research attempted to identify these steps in order to establish whether a particular occupational group was a 'profession'. It is not the intention here to determine which CAM practitioner groups are professions, given the limitations previously identified with the trait approach. Section 7.2, however, briefly examines the extent to which each CAM therapy has professionalised: that is, whether they have professional associations, training courses, voluntary registration, and codes of ethics and conduct.

According to demand theories of professionalisation the ultimate goal for occupational groups is occupational closure achieved through statutory regulation. Section 7.3 analyses whether CAM practitioner groups have actively sought statutory regulation as demand theories of professionalisation would predict.

Theory suggests that occupational groups seek occupational closure because of the associated economic benefits and social status. Section 7.4 examines the reasons why certain CAM practitioner groups sought statutory regulation. Section 7.5 identifies what (if any) disadvantages CAM practitioners associate with statutory regulation.

The final section discusses the extent to which demand theories of professionalisation, and an analysis which focuses on the activities of occupational groups, help to explain the regulatory process.

7.2 Professionalisation strategies among CAM practitioner groups

The main features of professionalisation are the establishment of professional associations, training courses (often formally accredited or university-based), voluntary registration with agreed standards of education, and a code of ethics. As this section shows all of the therapies in this study have professionalised to a large extent. For more detail on the key developments in the history of each therapy the reader should refer back to Chapter 5.

7.2.1 *Professional association(s)*

All of the CAM therapies discussed in this report have at least one established professional association, usually more. The timing of their establishment and primary objectives differ widely. For example the British Homeopathic Society (later the Faculty of Homeopathy) was established in 1843 to support the development of homeopathic medicine among registered medical practitioners. Its role was largely academic, akin to the one played by Royal Colleges for other medical specialities. In contrast, the National Institute of Medical Herbalists established in 1864 to represent qualified herbalists had a more political role (Denham, 2000). The association was in part a reaction to the Medical Act 1858 and the threat of legislation which would have outlawed herbal practice.

Some of the associations were set up to promote education and training in previously unknown therapies. For example the British Osteopathic Association (BOA) and the British Chiropractic Association (BCA) were established in the early 1900s to provide a membership organisation for graduates of the newly founded training colleges. Other associations provide training for and represent the interests of practitioners who are also practicing as statutorily registered health care professionals. For example the British Medical Acupuncture Society (BMAS) was established in 1980 to promote the use and understanding of acupuncture within medicine. Finally, some associations were created through mergers of existing associations (e.g. the British Acupuncture Council {BAcC} in 1995) or as a confederation of associations (e.g. the European Herbal Practitioners Association {EHPA} or the Council for Organisations Registering Homeopaths {CORH}).

A number of attempts have been made to establish a single professional association to represent complementary practitioners (e.g. British Register of Complementary Practitioners) but none has successfully registered a majority of CAM practitioners.

7.2.2 *Training courses*

Another common feature of professionalisation is the existence of formal institutionalised training in schools and colleges, often with external validation. In pragmatic terms, external validation enables students to access public subsidies available for tuition costs on recognised courses.

The majority of traditional medical practitioners worldwide are trained as apprentices, yet in the UK most CAM practitioners are trained in a formal educational setting. Until recently, the majority of courses were offered by private schools and colleges resulting in a lack of consistency and common standards (Foundation for Integrated Medicine, 2000, p88). It is only relatively recently that training schools have sought validation for their courses from higher education establishments. Higher and further educational establishments have been receptive due to pressure to expand their student numbers.

According to the General Chiropractic Council (GCC) “all the chiropractic education establishments ... have a degree programme validated by one of the UK universities” (General Chiropractic Council, 2000b, para 480). For example the Anglo European College of Chiropractic is an associate college of the University of Portsmouth and the McTimoney College of Chiropractic’s degree courses are validated by the University of Wales.

The first university based degree in herbal medicine started at Middlesex University in 1994 (McIntyre, 2004). Subsequent growth in the number of degree programmes has prompted herbalists from a variety of different backgrounds to work towards a common core curriculum for a four-year university course (House of Lords Select Committee on Science and Technology, 2000a, para 6.24). Acupuncture, osteopathy and homeopathy also have externally validated courses.

Many CAM practitioner organisations have their own system of accreditation. Accreditation is primarily a mechanism led by professional associations to support automatic registration of graduates. In a report funded by the Department of Health, Mills and Budd (2000) recommended that accreditation should be independent and should be carried out by a single accreditation body responsible for inspecting and approving training courses using agreed educational standards (Mills and Budd, 2000). At the time of the House of Lords’ Select Committee on CAM, acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy all had accreditation systems in place and were ahead of other CAM therapies in this regard (Department of Health, 2000d, para 23).

Osteopathy and chiropractic implemented accreditation as part of the system of statutory regulation. The independent accreditation system set up for non-medical acupuncturists in

the form of the British Acupuncture Accreditation Board was held up as an example of good practice by the Lords' Sub-Committee (House of Lords Select Committee on Science and Technology, 2000a, pp 59, 62) and is "very highly regarded" by the Department of Health (O'Farrell, 2004). Since 2002, the EHPA has an accreditation board to assess training standards reflecting the different traditions of Western, Chinese and Ayurvedic herbal medicine (Lampert, 2001). Homeopathy has been trying to establish accreditation procedures for some time. The CORH published proposals for accreditation in January 2005 but these have not yet been implemented.

7.2.3 *Voluntary registration*

Many professional associations develop a voluntary register of members in order to provide information to the public about the qualifications and standards of practitioners. Entry on the register is usually dependent on meeting specified entry requirements (including minimum training or qualifications) and complying with certain standards of practice. Each of the therapies examined here had a number of voluntary registers in operation at the beginning of the 1990s. Osteopaths and chiropractors formed a single register as part of the implementation of statutory regulation. Chiropractors had already made progress towards a single register through the formation of the Chiropractic Registration Steering Group in 1991. Osteopaths had established the General Council and Register of Osteopaths in 1936 on a voluntary basis, following failed attempts to establish a single register through legislation.

For herbalists a single register was seen as something that would come with the introduction of statutory regulation. In 1993 a number of herbal practitioner groups came together under the umbrella of the EHPA, others have joined subsequently. Each association continues to hold separate registers.

Non-medical acupuncturists created a single voluntary register with the establishment of the British Acupuncture Council (BAcC) in 1995. The Council unified five registering organisations who had been members of the Council for Acupuncture since 1980.

Non-medical homeopaths are in the process of establishing a single voluntary register. The Joint Meeting of Organisations Registering Professional Homeopaths (later known as the Council for Organisations Registering Homeopaths {CORH}) was established in 1999 to "work together for a single register" (Council of Organisations Registering Homeopaths, 2004b).

Registration usually requires a practitioner to meet explicit standards of education and training and comply with a professional code of ethics.

For the osteopaths, the process of developing unified standards was facilitated by the King's Fund Working Party on Osteopathy. Common standards for education and training were seen as an important prerequisite to seeking statutory regulation (General Osteopathic Council, 2000a). The Chiropractic Registration Steering Group established standards of education which it hoped would be recognized across Europe. These standards fed into the King's Fund Working Party on Chiropractic established in 1992.

The *Guidelines for Acupuncture Education* published by the BAoC were used by the British Acupuncture Accreditation Board as the basis for accreditation of courses. These standards, however, were not recognised by groups representing statutory health professionals practising western acupuncture or by the many groups representing traditional Chinese medical practitioners. More recently acupuncturists from different traditions have been working together to develop National Professional Standards.

Non-medical homeopaths worked with Healthwork UK to develop National Occupational Standards (later transferred to Skills for Health).¹⁶ The process of developing the standards involved joint working between associations and precipitated the formation of a common council to establish a single national register for homeopathic practitioners. The publication of the national occupational standards has been described as “a major leap forward” and “a watershed” (Society of Homeopaths, 2000b, para 676).

Representatives of the western herbal medicine professional bodies worked with Skills for Health, a government licensed body responsible for training standards, to define standards for the practice of herbal medicine (2002-2003). The standards were subsequently revised to include Chinese and Tibetan traditional medicine. The standards are intended to establish “a consensus on acceptable standards for herbal practitioners in their clinics” (European Herbal Practitioners Association, 2006).

7.2.4 *Code of ethics and conduct*

As well as requiring educational standards, voluntary registration is usually linked to compliance with a professional ethical code upheld by a complaints or disciplinary procedure. In a 1997 survey of CAM practitioner groups the Consumers Association found that all required members to abide by a code of practice and/or ethics and/or professional conduct, and umbrella groups made this a requirement for their member organisations (Bloomfield, 1997).

¹⁶ National occupational standards were originally part of a wider government initiative, led by the education department, to improve standards in further education. National Training Organisations were established to facilitate agreement on common standards for practice, education and training.

Both the GCC and the GOsC set and published codes of practice as part of the process of implementing statutory regulation. The Council for Acupuncture, the precursor to the BAaC, agreed a Code of Ethics and a Code of Practice, although it was unable to agree educational standards (British Acupuncture Council, 2000). Members of the BMAS are subject to the Society's code of practice which "sets out the professional duties and clinical standards expected of members" (British Medical Acupuncture Society, 2004).

Table 7.7 CAM therapies and the extent of professionalisation

	Homeopathy	Chiropractic	Osteopathy	Herbal medicine	Acupuncture
Professional association(s)	✓	✓	✓	✓	✓
Training courses with external validation	✓	✓	✓	✓	✓
Accreditation procedures	⊙	✓	✓	✓	✓
Single voluntary register	⊙	✓	✓	⊙	✓
Agreed national standards	✓	✓	✓	✓	✓
Code of ethics, conduct or practice	⊙	✓	✓	⊙	✓
Statutory self-regulation	✗	✓	✓	⊙	⊙

Key:

✓ In place

✗ Not in place

⊙ In development

The EHPA reported in 2000 that it was in the process of "agreeing a common code of practice enforced by stringent disciplinary measures" (European Herbal Practitioners Association, 2000a, para 20), but other herbal traditions such as Ayurveda insisted on their own code of ethics. So although there is a draft Code of Ethics and Complaints Procedures for herbal practitioners, there is still no agreed code in place. The CORH began the process of establishing a code of ethics for non-medical homeopaths in 2000 by identifying common elements from each of the codes in use by the different registering organisations (Council of Organisations Registering Homeopaths, 2004a). A draft code of ethics and practice was published for consultation in November 2004. Despite having in place codes

of ethics, conduct or practice, many of the voluntary registering bodies lack accessible complaints procedures and transparent disciplinary procedures.

By the end of the 1990s each of the five therapies had put in place or had in development most of the key organisational traits associated with a profession (see Table 7.7). Practitioners in all of the therapies, therefore, were to a great extent professionalised. But did CAM practitioner groups pursue this final stage of professionalisation? Did they all actively seek statutory regulation as demand theories of professionalisation would predict?

7.3 Seeking statutory self-regulation

All CAM practitioner groups examined here have taken significant steps to professionalise. Demand theories of professionalisation would expect these groups to pursue statutory regulation as a final step in the process. This section reviews the evidence that organized CAM practitioner groups have been actively mobilized in pursuit of statutory self-regulation. There are a number of possible legislative routes open to CAM practitioners. Firstly through a single Act of parliament (either a Private Members' Bill or a government-sponsored bill) create a new council. Secondly by Order of Council be included in the Healthcare Professions Council (HPC) (or prior to 1999 the Council for Professions Supplementary to Medicine). Thirdly under Section 60 of the Health Act 1999 form a new Council.

As we saw in Chapter 4 some CAM practitioners made attempts in the past to gain statutory regulation similar to that enjoyed by the medical profession. None of these were successful. Here I examine the contemporary activities of CAM practitioner groups in the five therapies chosen for inclusion in the study in order to establish whether they have actively sought statutory regulation.

Both osteopathy and chiropractic were successful in gaining statutory regulation in the early 1990s. The perception of key stakeholders was that the impetus came from within the professions themselves. For example a Department of Health official said that "Osteopathy was the leader...they'd been trying since before the last war to gain some form of statutory recognition" (Brown, 2004, para 139). He recounted that "there were a number of different osteopathic organisations...they came together in one umbrella group. And that group, its remit was essentially to prepare for statutory regulation" (Brown, 2004, para 151). The Chair of the Herbal Medicine Regulatory Working Group (HMRWG) also thought that "if you look at osteopathy and chiropractic...the driver actually came from within the professions themselves...They saw regulation as a way to improve the standards" (Pittilo, 2004, para 45).

The main osteopathic groups were active in the 1980s to garner support for their call to statutorily regulate the profession. In 1986 they successfully had a bill introduced to the House of Commons under the ten-minute rule which served to establish all-party support (King's Fund, 1991). It was ultimately the establishment of an independent working party by the King's Fund that galvanised support for the profession's demands.

The King's Fund Management Committee announced in the autumn of 1989 that they were establishing a Working Party chaired by Sir Thomas Bingham, later Lord Chief Justice of England and Wales, to look into the issue of statutory regulation of osteopaths. The first meeting was held 5th December 1989. The Working Party drafted a Bill which was first introduced into the House of Lords by Lord Walton on 17th December 1991. It was amended in Committee by the House of Lords and had its Second Reading on 31st January 1992. However the election was called before the final committee stage was passed. The Bill was introduced into the House of Commons in the new session by Mr Malcolm Moss MP as a Private Members' Bill. It came second in the ballot of members and has its first reading on 10th June 1992. It had its second reading on 15th January 1993. The Osteopaths Bill passed through its third reading in the House of Commons on 7th May 1993 and has been described as the "largest private Members' Bill ever to be brought to a successful conclusion" (Standen, 1993). This led the way for other CAM practitioner groups.

In 1989 when the King's Fund were establishing the Osteopathy Working Group they considered whether to address chiropractic at the same time. They decided against this but agreed that once the work with the osteopaths was finished they would look at the chiropractors (Maxwell, 2005), which they subsequently did in 1992. In 1990 the BCA had already begun to hold regular meetings with the Department of Health, and in 1991 formed the Chiropractic Registration Steering Group to unify the profession in advance of attempts to secure statutory regulation (Hutchinson, 1994). They were also active in trying to win over the medical profession, and keen to have independent endorsement for proposals to regulate them.

In 1993, with the King's Fund report published, chiropractors were well positioned to lobby parliament to support a Private Members' Bill. David Lidington MP came fourth in the ballot and introduced the Bill to the House of Commons on 16th December 1993. Lord Walton, a member of the King's Fund Working Party, introduced the Bill to the House of Lords (Hutchinson, 1994). It had its second reading on 18th February 1994 and passed its third reading on 6th May 1994. The passage of the Chiropractors Act 1994 was

according to the GCC the “outcome of more than 20 years campaigning by the chiropractic profession” (General Chiropractic Council, 2000a, p 93).

Herbalists have also been active in seeking statutory regulation (European Herbal Practitioners Association, 2000a, para 20). In evidence given to the House of Lords in 2000 they indicated that they would be making an application for statutory self-regulation “within the next few months” (European Herbal Practitioners Association, 2000b, para 714). The process has in fact been slower and taken a somewhat different route. The EHPA was formed to unify the profession, a necessary precursor to seeking statutory regulation (McIntyre, 2004). It explicitly acknowledged that the aim of their professionalisation activities (described above) such as establishing a core curriculum, an accreditation board, drafting a code of ethics, introducing disciplinary procedures and a scheme of continuing professional development was “to establish the conditions which could support an application for statutory self-regulation for herbal medicine” (Lampert, 2001). Having established support among its members, the EHPA had “preliminary discussions” with the Department of Health in December 2000 (Lampert, 2001, para 3).

As shown above non-medical acupuncturists have professionalised more completely than either herbal medicine or homeopathy. The BAoC’s unified system of voluntary registration and the British Acupuncture Accreditation Board were held up as examples of best practice in the House of Lords’ Select Committee Report (House of Lords Select Committee on Science and Technology, 2000a, p 60). Yet in contrast to the herbalists, these activities were not viewed as preconditions for statutory regulation. Michael O’Farrell, Chief Executive of the BAoC, claimed “we haven’t lobbied for regulation at all. We’ve been supportive of regulation, we’ve concentrated on having our own voluntary self-regulation” (O’Farrell, 2004, para 235). It seems that only after having been identified by the Foundation for Integrated Health as a profession suited to statutory regulation the BAoC began informal discussions, both within the profession and with others including the Department of Health, about the options. They set up a Regulation Action Group with expert advisers to look at the issues in more depth (British Acupuncture Council, 2000, para 769).

Following the recommendations of the House of Lords’ inquiry and the government’s response, which agreed that acupuncturists should move towards statutory regulation, the BAoC participated actively in the work of the Acupuncture Regulatory Working Group (ARWG) (British Acupuncture Council, 2004b, para 6). Throughout the process they responded to events and proceeded only with the support of their members. The BAoC leadership have been very concerned to “carry the membership” in moves towards statutory self-regulation, in part because initial debates showed that opinion was

“somewhat divided” (British Acupuncture Council, 2000, para 769). The BAAC undertook a consultation with its members in 2001 on the issue of statutory self-regulation, culminating in a vote which mandated the leadership to “pursue a suitable route to statutory self-regulation”. The Chief Executive was eager to stress that “at each stage there’s been no pushing” (O’Farrell, 2004, para 235). They were not pro-active in seeking statutory regulation at any point.

Among the five therapies analysed here non-medical homeopaths have perhaps been the least active in activities to secure statutory regulation for their profession. Statutory regulation has been considered a possible ‘next step’ but the main priority of the practitioner groups has been the establishment of a single voluntary register and accreditation board (Society of Homeopaths, 2000b, para 676). The House of Lords’ report also recognised that the homeopaths were the “least enthusiastic”, but urged them to consider the benefits of statutory regulation (House of Lords Select Committee on Science and Technology, 2000a, p 51). Although the Department of Health had no plans for the statutory regulation of homeopathy in spring 2004, they were open to the possibility if approached by the profession (Sidwell, 2004). Non-medical homeopaths appear to remain reticent. In their response to the Department of Health’s consultation on statutory regulation for acupuncture and herbal medicine, the CORH wrote “...the homeopathy profession may consider, at some point in its future, whether it also wishes to explore whether statutory self-regulation would be a route it wishes to take” (Council of Organisations Registering Homeopaths, 2004b, para 18). Maggy Wallace, Chair of the CORH, although personally keen that homeopaths should not miss the chance presented by the government’s actions to regulate acupuncture and herbal medicine, admitted that the homeopaths probably were not ready for such a move (Wallace, 2004, paras 93-99).

The views expressed by organized representatives of practitioner groups and in their official documents indicate that chiropractors, osteopaths and herbalists were actively pursuing statutory self-regulation. However, acupuncturists and homeopath have not actively sought statutory self-regulation. The next section analyses the benefits of closure put forward by practitioner groups.

7.4 The need for a profession

So far, in examining the relevance of the demand theories of professionalisation to the development of regulation of CAM practitioners in the UK, we have established that all therapies had professionalised but only some actively sought statutory self-regulation. Demand theories claim that occupational groups seek statutory self-regulation in order to

gain the benefits associated with closure and monopoly. Closure is achieved when the practice or use of title is restricted in law. This section analyses CAM practitioners' views on the benefits associated with economic and social closure.

7.4.1 *Economic closure*

Economic theories would expect economic benefits of professionalisation to be of most interest to practitioners. There are a number of ways in which statutory regulation could generate economic benefits for CAM practitioners:

1. By limiting entry the profession are able to control supply and charge higher prices for their services.
2. If certain functions are protected this gives the profession a monopoly over this service.
3. Protection of title means that consumers can be confident that those advertising their services are qualified and may result in increased demand.
4. CAM services provided by regulated practitioners are more likely to be included in reimbursable benefits covered by private health insurers, to be funded by or integrated into the NHS.
5. Conventional practitioners are more likely to refer patients to regulated CAM practitioners.

None of the practitioner groups directly mentioned that higher personal income would be a benefit of statutory regulation. The costs of regulation were, however, a major concern (see Section 7.5.4).

Herbalists were the only group of CAM practitioners seeking protection of function under statutory regulation. Statutory regulation would grant exclusive dispensing rights of certain potent herbs. This would strengthen the economic position of herbalists allowing them exclusivity over herbal remedies and preparations. Andrew Chevallier, former President, of the National Institute of Medical Herbalists, and Senior Lecturer in Herbal Medicine at Middlesex University talking on behalf of herbalists stated that:

...We expect that if we should achieve statutory self-regulation, then registered professional herbal practitioners would be able to continue using those herbs. That would be a major incentive for herbal practitioners to be registered (European Herbal Practitioners Association, 2000b, para 728).

Practitioner groups hoped that statutory recognition would increase public confidence in the profession. For example osteopaths expected that regulation would give members of the public “who hitherto may have been reluctant to consult an osteopath the confidence to do so” (General Osteopathic Council, 2000a, p102). David Tredinnick MP claimed this had already happened “The increase in the demand for chiropractic and osteopathy is evidence of the benefits of placing osteopathy and chiropractic on a statutory basis.” (Tredinnick, 2000, p290). Few other statements were as explicit that public confidence would translate into increased demand for services.

Many CAM practitioners thought statutory regulation would give them greater access to public funding. There was an expectation among chiropractors and osteopaths that greater access to NHS funding would follow statutory regulation, either through new employment opportunities or increased contracting. During oral evidence to the House of Lords’ the General Osteopathic Council stated that “We would envisage the provision of osteopathy would ultimately be established across all practices within a PCG [primary care group] so that a comprehensive service becomes available to the NHS” (General Osteopathic Council, 2000b, para 427). But progress has been slow creating frustration. The General Chiropractic Council stated that:

...we have not been able to move some things forward as fast as we would like to. We are as anxious as the osteopaths profess themselves to be to work with the NHS to make chiropractic accessible to a wider public (General Chiropractic Council, 2000b, para 488)

Despite the experience of osteopathy and chiropractic, other practitioner groups continue to mention increased opportunities for integration and funding under statutory regulation. For example the Chief Executive of the BAoC thought statutory regulation would give new acupuncture graduates “the opportunity if they wish to more easily work in the NHS” and “encourage the decision-makers and the private medical insurers to think more objectively about the members that are regulated professionals” (O’Farrell, 2004). The Society of Homeopaths saw a single national register of practitioners with agreed standards as the basis for defining NHS access (Society of Homeopaths, 2000a, p 219). The Foundation for Integrated Health also suggested:

Some of them [CAM practitioners] see the benefits; they can take pride in being part of an organised profession and there’s also the aspect of potentially being able to work within the NHS or in an integrated way (Jack, 2004, para 337).

Most groups recognized that lack of evidence of efficacy and cost effectiveness was also a major barrier to funding from the NHS. Interestingly this was not seen to be an issue for private health insurers.

Some stakeholders believed that integration of CAM within the NHS was more likely once practitioners were statutorily regulated. For example the BAaC saw a single register of acupuncturists as a means of “facilitating the integration of acupuncture into mainstream healthcare” (British Acupuncture Council, 2004b, para 29). Osteopaths also saw regulation as necessary for integration. The General Osteopathic Council (GOsC) stated that:

We hope...that the statutory regulation of osteopathy will allow the profession to gain increasing acceptance, so that it will become more available to members of the public as an integrated part of the nation's healthcare system (General Osteopathic Council, 2000b, para 411).

Chiropractic professional associations were particularly keen that the government should take seriously the “integration of regulated, non-orthodox medicine into the NHS” (British Chiropractic Association, 2000, p 31) and felt that with professional regulation and evidence in place there was no longer an impediment to this happening (College of Chiropractors, 2000, p 412). Herbalists believed the way to satisfy public demand for CAM therapies on the NHS was to employ practitioners who work within a code of ethics (European Herbal Practitioners Association, 2000a, p 79).

In acupuncture and homeopathy, where significant numbers of statutorily regulated health care professionals already practice therapies within the NHS, there were worries that proposals for statutory regulation of lay or traditional practitioners would diminish or undermine present integration (Faculty of Homeopathy and British Homeopathic Association, 2004). The BMAS believed that “the progress made in integrating acupuncture into modern health care, and the potential to further that integration will be seriously impaired under the proposals as drafted” (British Medical Acupuncture Society, 2004, para 62). These practitioners were keen to resist further regulation or additional training. The Medical Director of the BMAS asked:

Are you going to achieve more public protection by more regulation of these people who are already regulated. Or are you going to diminish integration of a useful technique? That is the balance I am not sure about (Cummings, 2005, para 256).

As well as precipitating changes in the official policies of the NHS, regulation was also expected to influence the behaviour of referring physicians. Guidance issued by the British Medical Association (BMA) in 1999 made it clear that general practitioners (GPs) are able

to delegate treatment to CAM practitioners who are non-statutorily regulated (General Practitioners' Committee British Medical Association, 1999). However, GPs still retain responsibility and liability for the patients' care. GPs therefore require some means to judge the competence of those to whom they delegate care. It is therefore not surprising that osteopathy and chiropractic are among the therapies most frequently referred to by GPs. Herbalists believed increased referrals would follow statutory regulation (Register of Chinese Herbal Medicine, 2000; Herbal Medicine Regulatory Working Group, 2003, para 504). Other practitioner groups were less interested in referrals, preferring perhaps to ensure that patients had the right to directly access their services as at present.

Arguments about the link between regulation and referrals were also made by conventional health care professionals. For example those doctors who wish to refer their patients with greater ease to CAM practitioners argue that statutory regulation (or at a minimum a single voluntary register) is vital. The Chair of the NHS Alliance, a representative organisation of primary care organisations and those who work in primary care, admitted "professionals inside the conventional camp" have said to CAM practitioners "You really have got to {regulate} if you want us to refer our patients to you. Otherwise we don't quite know what the quality control is" (Dixon, 2005b, para 15). For official bodies such as the Royal College of General Practitioners, "regulation... makes it much easier...to issue guidelines, to make patient referrals and to make more use of the CAM therapies that are available" (Royal College of General Practitioners, 2000b, para 1508). Ministers echoed the views of the medical profession "Without proper self-regulation it is very difficult for many GPs and people across the health service to feel confident in terms of CAM therapies" (Department of Health, 2000c, para 1883).

According to the views of the leaders of CAM practitioner groups, of the five possible ways in which regulation can generate economic benefits examined here, greater access to NHS funding is the most important to practitioners. Other commentators are sceptical that statutory regulation will result in any such benefits (Stone, 1996). The next section examines the perceived social benefits of occupational closure.

7.4.2 *Social closure*

The sociological literature gives more emphasis to the desire for status and recognition by occupational groups seeking statutory self-regulation. In this section we review whether a desire for status lay behind the demands for statutory recognition made by CAM practitioner groups. According to the Department of Health "Status is associated with both

public trust and confidence in CAM practitioners and with recognition from orthodox medicine” (Department of Health, 2000d, para 69).

For some CAM practitioners status is about equality with the medical profession and other health care professionals. The Faculty of Homeopathy talked about regulation creating “a level playing field” (Faculty of Homeopathy, Homeopathic Trust and British Homoeopathic Association 2000, para 659). The Chief Executive of the Foundation for Integrated Health recounted the arguments he had often heard practitioners make:

We believe strongly that our profession has something to offer and that if we were statutory regulated on the same basis as doctors and nurses we would be their equal, wouldn't we?' ... 'We want to be their equal' ... 'We believe we are their equal' and that would be the icing on the cake to say 'Yes, we are their equal' (Fox, 2004).

The Department of Health made it clear that, “if it [CAM] aspires to be an equal player with other forms of NHS treatment it must meet the same standards required of them” (Department of Health, 2001a).

Practitioners are willing to make sacrifices in return for enhanced status. For example acupuncturists see the potential additional costs of statutory regulation as “a fair price for the enhanced status” (Acupuncture Regulatory Working Group, 2003). Osteopaths have “tolerated it [the lengthy process of registration] because they do actually want the privilege of self-regulation as a profession” (General Osteopathic Council, 2000b, para 445). They were “willing to go the extra mile” in order to “associate themselves with the highest standards in healthcare” (Brown, 2004).

Improved professional status and respect is presented as one of the benefits of regulation (Budd and Mills, 2000). Many of the responses to the consultation on the statutory regulation of herbal medicine and acupuncture supported regulation as a means to “enhance the status of the herbal medicine and acupuncture professions” (Department of Health, 2005b). The GOsC believes that “statutory regulation has enhanced the trust and respect afforded us [osteopaths] by the medical profession” (General Osteopathic Council, 2000b, para 423).

There are others outside of CAM who turn the argument on its head, claiming that the government should not ‘regulate rubbish’ because it gives legitimacy to therapies that have no basis in science and no evidence of efficacy. For example the Royal College of General Practitioners wrote, “It also seems important that regulation is not seen as attributing credibility to otherwise incredible forms of treatment” (Royal College of General Practitioners, 2000a, p 303).

The ability to create a strong cohesive professional identity and maintain the reputation of the profession is important to practitioners. The process of professionalisation was felt to significantly contribute to a strong professional identity (British Acupuncture Council, 2000, para 765). The herbalists thought that “separate councils would allow individual herbal traditions to develop their profession and foster coherence” (Herbal Medicine Regulatory Working Group, 2003, para 180). Representatives of the acupuncture profession felt the need to achieve “a coherent and cohesive acupuncture profession prior to any collaborative or joint enterprise” with herbal medicine (Acupuncture Regulatory Working Group, 2003, para 166). Most practitioner groups felt professional identity could actually be undermined by the creation of a joint council or an umbrella CAM Council.

Reputation is maintained through enforcing a code of ethics or practice. Statutory regulation is seen to give ‘real teeth’ to the process by enabling the profession to strike an errant practitioner from a register and prevent them from using the professional title (General Osteopathic Council, 2000b, para 416). Statutory regulation gives professions a means by which to safeguard their reputation and dissociate from unqualified and poorly trained practitioners (Ayurvedic Medical Association, 2000; Faculty of Homeopathy, Homeopathic Trust and British Homoeopathic Association, 2000).

Professionalisation and statutory regulation are supported by CAM practitioners for a number of reasons relating to economic and social closure. For CAM practitioners the major benefits of closure were the opportunity to treat NHS-funded patients, either on contract or integrated as part of the health care team, and the status and recognition from other health care professionals.

Support for statutory self-regulation was not universal. The final section analyses the extent of opposition to statutory regulation.

7.5 Opposition to regulation

A number of concerns about the impact of statutory regulation were expressed by CAM practitioner organisations. These included restricting patient choice or access, reducing autonomy, stifling creativity and innovation and driving practitioners underground because of the costs of registration. These consequences were not viewed as inevitable but rather as dangers associated with “a heavy handed or abrupt approach”, thus it was urged that “regulation should be introduced progressively and in consultation with representative therapist groups” (Royal London Homoeopathic Hospital, 2000, p195). Reputedly practitioners frequently voiced concerns about over-regulation (Fox, 2004). This section looks at the major reasons for opposing regulation in more detail.

7.5.1 *Restricting choice and access*

Some CAM practitioner groups were worried that statutory regulation would restrict access and choice for patients by limiting the right to practise to registered practitioners. These concerns were fuelled by the experience of osteopaths and chiropractors. Some existing practitioners who applied for entry on the new registers under grandparenting schemes were refused registration. The chiropractors who were excluded from the register continued to practise as cranio-sacral therapists. It is likely some practitioners will find themselves excluded when new registers are created even if there is automatic entry on the basis of qualifications. The possibility of exclusion from a statutory register was a worry to practitioners. Exclusion has serious consequences, restricting one's ability to practise, use the protected title and earn a living. Students in training were also anxious that their qualifications might not be accredited by the new council (Hansard, 6 May 1994).

The Chair of the ARWG said that "There was a real concern that there would be hurdles that were difficult for people who were safe practitioners who had practised over a long period of time to go over" (Pittilo, 2004). Members of the BMAS were concerned that if entry criteria to the new acupuncture register were defined by non-medical acupuncturists the right of statutorily regulated health professionals to practise acupuncture or use the title 'acupuncturist' might be restricted (Cummings, 2005, para 82).

7.5.2 *Domination and loss of autonomy*

Many CAM practitioners work in single-handed practice and are attracted to the work because of the freedom and autonomy it allows them. According to Michael Fox, Chief Executive of the Foundation for Integrated Health, many CAM practitioners hold the view that "We want to work on our own" and some that "We don't need regulation" (Fox, 2004).

Concerns were expressed that statutory self-regulation might result in the therapy (and therapists) being dominated by orthodox medicine. The Institute for Complementary Medicine (ICM), a registered charity set up to provide the public with information about complementary medicine and which administers the British Register of Complementary Practitioners, was particularly vociferous in its condemnation of the House of Lords' recommendations to statutorily regulate acupuncture and herbal medicine. It claimed that this would result in CAM practitioners coming "under the direct control of the medical profession" and being reduced to "the level of auxiliaries" (Baird, 2001, para 51). Such ideas are supported by academics. For example Saks (1998) interprets the (positive) change in the attitude of the medical profession towards CAM as an "attempt to maintain its

hegemony through incorporation and subordination” (Saks 1998, cited in Williams, Jack et al., 2004).

Concerns about domination are perhaps not without cause. The Faculty of Homeopathy while supporting the statutory regulation of non-medical homeopaths stated that they should be registered as homeopathic practitioners because they “do not do the same jobs” as homeopaths with medical training. They did not make it clear how these homeopathic practitioners would differ but the implication was that they would operate at a lower grade (Faculty of Homeopathy, Homeopathic Trust and British Homoeopathic Association, 2000, paras 651-3).

Furthermore, as voluntary self-regulating professions, CAM practitioners have been used to a high degree of professional autonomy, including the ability to determine the content of their practice. Statutory regulation was associated with a potential loss of autonomy (British Acupuncture Council, 2000, para 769). A common view was that CAM practitioners would have to “sell out”, by giving up their holistic approach and accepting a narrower scope of practice, in order to gain support for statutory regulation (Stone, 2005b, para 53). Today’s osteopaths and chiropractors are considered more acceptable by allies of biomedicine because they “have given up the claims (which they made strongly for 100 years or more) that their treatment would cure or alleviate almost any disease in any part of the body” (Healthwatch, 2000, p122). Acceptance of a role complementary to biomedicine appears to be important in gaining the support of orthodox medicine for regulation.

Statutory regulation was seen by many therapists as a threat to autonomy and provoked fears of subordination to medicine.

7.5.3 *Stifling creativity and innovation*

A further negative aspect of regulation is the threat that standardisation of practice poses to CAM practitioner’s individual creativity and the ability of therapies to innovate (Williams, Jack et al., 2004). The current diversity of practice in CAM arises because treatment is individualised for each patient and there are a range of philosophical underpinnings within each therapy. In Stone’s view “This plurality would almost certainly be lost in a statutory scheme, which would gravitate towards the most established or dominant schools of thought to the exclusion of opposing views” (Stone and Matthews, 1996). The current trend of diversification of practice with new sub-specialities constantly appearing would certainly be curtailed by statutory regulation.

The Department of Health was aware of practitioners anxiety: “...there was some concern about stifling creativity and practising in a more individual kind of way... I think for some

practitioners they found it a little bit threatening” (Sidwell, 2005, para 160). In the proposals for the statutory regulation of herbal medicine and acupuncture the Department of Health addresses the issue of how statutory regulation would preserve diversity. They highlight that a “shared Council would support practitioners who work across professional boundaries, while preserving and respecting individual traditions within the herbal medicine and acupuncture professions” (Department of Health, 2004a, para 53). The EHPA were keen to ensure that the structure of the new council would grant “the individual disciplines and traditions sufficient autonomy, control and influence over the education and registration standards of their respective traditions/modalities” (European Herbal Practitioners Association, 2004, para 13). Different traditions and approaches existed in chiropractic prior to the Chiropractors Act 1994. In the closing debate on the Bill, Tom Sackville MP, Parliamentary Under-Secretary of State for Health, reassured practitioners that “Increasing each chiropractor’s sense of belonging to a single profession should not make practitioners fearful of losing their identity as particular types of chiropractor” (Hansard, 6 May 1994).

7.5.4 Cost of registration

By far the largest concern, measured in terms of the number of times and range of stakeholders that mentioned it, was the cost of statutory regulation. Practitioners were concerned both about the expense of setting up statutory regulation and the cost of registration fees under a new system (British Acupuncture Council, 2000, para 769; Acupuncture Regulatory Working Group, 2003, para 33).

Members of the ARWG were “very concerned about the cost”. It was more of an issue than “philosophy or the design of a CAM Council” (Chan, 2005). Concerns about the costs of statutory self-regulation were also prominent in the discussions of the HMRWG (Herbal Medicine Regulatory Working Group, 2003, para 164). Due to the small number of herbalists the cost per capita of running a statutory regulatory body would be high (about £468 per annum compared to £290 for doctors and £60 for registrants of the Health Professions Council). Herbalists argued that “It is not in the interests of either the public or practitioners for members of the herbal medicine profession to be charged disproportionately higher fees than other healthcare professionals” (Herbal Medicine Regulatory Working Group, 2003, para 164).

The GOsC advised other CAM practitioners to “consider the relative size of the profession, and whether or not there is sufficient resources and infrastructure within that profession to cope with the demands of statutory regulation” (General Osteopathic

Council, 2000b, para 413). They stressed that costs of operating a regulatory body would be high for a small profession (General Osteopathic Council, 2000b, para 466; General Osteopathic Council, 2004b, para 18). Concerns about the cost of introducing statutory regulation were also voiced by practitioners and students of herbal medicine and acupuncture in response to the consultation by the Department of Health (Department of Health, 2005b). Costs continue to be discussed as implementation plans are drawn up for a new voluntary register for homeopaths and a statutory register for acupuncturists and herbalists.

For statutorily regulated practitioners the costs of dual registration are a concern. They are reluctant to pay an additional fee to a new council regulating CAM therapies on top of the fees they already pay to the General Medical Council (GMC) or other statutory regulator. The Faculty of Homeopathy, representing medical homeopaths, argued there should be “no charge for those already statutorily regulated to appear on the CAM Council list” (Faculty of Homeopathy and British Homeopathic Association, 2004). The BMAS lobbied that the fee for their members to join a statutory register of acupuncturists should be no higher than £30 per annum. They argued that “the proposed costs of regulation...will act as a major disincentive and barrier to the practice of acupuncture by regulated health professionals in the NHS” (British Medical Acupuncture Society, 2004). In an attempt to assuage the concerns of the western acupuncturists the ARWG put forward the idea that acupuncturists, who were already statutorily registered by another body, could be listed for a nominal fee and have the right to use the protected title.

Anecdotally many CAM practitioners practise more than one therapy. A statutory register for each therapy would mean that “multi-disciplinary practitioners would have to pay four or five sets of registration fees” (Williams, Jack et al., 2004). A federal structure or umbrella council was seen to have advantages for these practitioners (Prince of Wales's Foundation for Integrated Health, 2005) although important multidisciplinary practice is likely to diminish over time. With the move towards full degree courses in acupuncture, herbal medicine and homeopathy, recently qualified practitioners are more likely to remain specialised in one therapy in future.

The professional associations were also concerned about cost. Uncertain about their own future role, they were particularly worried that if the costs of registration were too high practitioners would be less willing to become members of a professional association (Department of Health, 2005b). The ARWG report speculated that “As their [associations] fees would represent the optional part of the overall package, it is likely to be the voluntary membership of the association which will suffer if the combined cost burden becomes

onerous” (Acupuncture Regulatory Working Group, 2003, para 243). This issue was also mentioned in the BAAC’s consultation response, which stated that:

Our underlying and deeper concern about cost is that...there may be serious long-term consequences for the continued existence of the professional associations which we believe are essential partners in the delivery of effective statutory regulation...the cost of regulation will undermine the professional associations which are vital to the success of the regulatory partnership as well as to the preservation of individual styles and traditions (British Acupuncture Council, 2004b, para 24).

Of all the reasons for opposing statutory regulation the issue of cost was most important to practitioners and professional associations alike. The final section of the chapter discusses the findings of the analysis, and considers how useful demand theories of professionalisation are to explain the regulatory process.

7.6 Discussion

The sociological literature views statutory regulation as the culmination of a process of professionalisation. This study has found that while all CAM practitioner groups pursued professionalisation strategies they did not necessarily seek statutory regulation. Both homeopaths and acupuncturists developed many of the features of a mature profession but neither actively sought statutory recognition. These findings highlight the fact that not all professions make demands for statutory regulation. Other examples of unregulated professions might include university lecturers and librarians. There are also cases of occupational groups which are regulated but which have not professionalised, in the sense used here. Examples of regulated non-professions might include gangmasters, gas appliance fitters, and adventurous activity providers who are required to be licensed by the state.

The CAM practitioner groups which sought statutory regulation did not necessarily do so for the reasons cited in the economic literature (e.g. to extract monopoly rents). Of course, income maximisation may have been an underlying motivation, but this was not spoken about publicly. This study identified a myriad of benefits of closure. It is perhaps not surprising in the context of the NHS that access to public funding was the most important economic benefit associated with occupational closure for CAM practitioners.

The history of medicine charts the battles that have been fought between practitioners over definitions of legitimate practice. This study found a general expectation among CAM practitioners that statutory regulation would ensure equal treatment *vis a vis* conventional

medical practitioners. This may reflect a desire to reverse the dominance of biomedicine and orthodox medicine over CAM that has existed for the past 125 years. Some stakeholders believed CAM practitioners would gain the confidence and respect of doctors if statutorily regulated. Past experience suggests that demands for statutory regulation are more successful if supported by the medical profession. Professional confidence in CAM may therefore be a prerequisite to statutory regulation rather than a consequence of it.

Demand theories treat occupational groups as cohesive entities. The assumption is that professionalisation and statutory regulation are in the interests of all practitioners. In this study the evidence suggests that while the leaders of organised CAM practitioner groups favour statutory regulation, they do not necessarily carry the full support of practitioners.

The data in this study consists of the views of leaders of practitioner groups. It therefore does not accurately reflect the views of grassroots practitioners but relies on second-hand reports. Despite this limitation the study was able to identify a number of concerns held by the wider community of practitioners. There were fears that multi-disciplinary practice and individualised approaches might be threatened by the requirements to enter a register and conform to standardised modes of practice. Both the leaders of the professional associations and practitioners were concerned about the costs of statutory regulation but for different reasons. Associations were worried about their own future. If practitioners were required to pay high statutory fees they might opt not to join a professional association. Practitioners were concerned that they would have to pay twice – once for membership of an association and once for registration – and felt that fees might be unaffordable (if similar in magnitude to those charged by the GOsC and the GCC).

In general, a picture emerges of leaders of practitioner organisations driving the process, somewhat removed from the concerns or interests of their members. The tension within professions between ‘corporatists’, who are prepared to accommodate public policy objectives in order to determine standards themselves and police their own ranks, and ‘liberals’, who value individual entrepreneurialism and wish to remain free from interference from government or professional bodies, has been identified elsewhere (Tuohy, 1976). Future research should be clear to distinguish between the views, interests and concerns of leaders of professional associations (corporatists) and those of grassroots practitioners (liberals).

Overall, the approach adopted by this study has allowed for an exploration of the role played by occupational groups in achieving statutory regulation. It has provided a fairly robust explanatory framework for the development of chiropractic and osteopathy. The proposals to introduce statutory regulation for herbalists can also be explained using the

framework of demand theories of professionalisation. The herbal profession unified under the umbrella of the EHPA and, although they had not established a single register and there remained several disaffiliated herbal groups, they lobbied for statutory self-regulation.

Demand theories, however, do not explain why acupuncture is being brought under statutory regulation despite the lack of demand for this from practitioner groups. It appears there are other factors influencing the policy process which are not revealed by using this analytical lens. In the next chapter I use the supply theories of professionalisation to see whether these can further illuminate our understanding of why some CAM practitioner groups have gained statutory recognition or are in the process of achieving it.

8 THE SUPPLY OF PROFESSIONAL REGULATION

8.1 Introduction

The previous chapter analysed the introduction of statutory regulation for CAM practitioners in the UK using demand theories of professionalisation. It provided some useful insights into the process and gave a partial explanation for the differences between therapies. This chapter explores whether the application of supply theories of professionalisation to these same cases will provide further illumination and explanation.

Supply theories of professionalisation suggest that professions develop in response to the demands of the state. From this perspective it is the state that determines whether occupational groups are statutorily regulated. The state is treated as a unified entity by the majority of these theories. The 'state' is usually understood to include the government or executive, the legislature and the judiciary. The term 'state' is generally used in this chapter though specific reference is also made to the government, or the Department of Health or the House of Lords (as applicable). This chapter re-analyses the five cases of acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy using the supply theories of professionalisation as an interpretive framework (set out in Chapter 5). The focus within the data is on government policy documents, parliamentary debate and official statements by civil servants and politicians, as well as interviews with government officials and peers.

The chapter examines how and why the state's approach to the regulation of CAM practitioners has changed over time. Sections 8.2-8.4 examine the strategies employed by the state and identifies three phases of state action. In the late 1980s and throughout much of the 1990s the state was passive, rewarding aspiring professions who met certain criteria. In response to wider concerns about risks to public health the state adopted a more proactive approach, supporting professionalisation activities among CAM practitioners. At the end of the study period the state's concerns about over-regulation mean it promotes a proportionate approach to risk regulation which emphasises the costs and benefits. Section 8.5 argues that throughout the period of study a desire to protect consumer choice has remained a strong countervailing argument to regulation. Finally Section 8.6 examines how the regulation of our five cases has been influenced by state action. The chapter concludes with a discussion of the findings. It considers how useful supply theories of professionalisation are in explaining which CAM practitioner groups are subject to statutory regulation.

8.2 Setting criteria for aspiring professions

The state's involvement in CAM has a longer history than can be traced here. The analysis begins in the mid-1980s when government Ministers and parliament began to actively discuss the regulation of CAM practitioners. Table 8.8 sets out a chronology of key events in the development of regulation.

In the 1980s the Conservative government was aware of the increasing use made of CAM by the general public and was coming under pressure to grant statutory regulation to some practitioners. Yet the state remained fairly passive at this time, expecting practitioners to organise themselves. Parliamentary Under-Secretary of State for Health Tom Sackville MP recalled that:

In 1985, Lord Glenarthur, the Under-Secretary of State in what was then the Department of Health and Social Security, outlined the criteria that the Government expected professions of non-conventional medicine to fulfil before being considered suitable for statutory regulation (Hansard, 15 January 1993).

The criteria were first articulated in the mid-1980s and elaborated in successive documents and speeches.

The criteria that the government set out at this time were that the profession in question should be based on a systematic body of knowledge, have in place accredited training courses and a credible and appropriate system of voluntary regulation, and agree among themselves on the best way forward (General Osteopathic Council, 2000b, para 413).

In 1987 Baroness Trumpington, Parliamentary Under Secretary of State at the Department of Health and Social Security, said in a speech to the Royal Society of Medicine that:

Some people argue that it is the Government's responsibility to register alternative therapists. It may come to that one day, but if it does it will be because the alternative community has been unable to put its own house in order (Trumpington, 1987).

Table 8.8 Overview of key dates in the regulatory process

Date	Description of event or publication
1986	British Medical Association (BMA) report on 'alternative therapy' published (British Medical Association, 1986)
May 1986	Bill introduced to House of Commons under ten-minute rule on regulation of osteopaths and chiropractors
5 December 1989	King's Fund Working Party on Osteopathy convened
1991	King's Fund Working Party on Osteopathy report and draft bill published (King's Fund, 1991)
17 December 1991	Private Members' Bill on osteopathy introduced to the House of Lords
March 1992	King's Fund Working Party on Chiropractic convened
7 May 1993	Osteopaths Act passed
1993	Second BMA report on 'complementary medicine' published (British Medical Association, 1993)
1993	King's Fund Working Party on Chiropractic report and draft bill published (King's Fund, 1993)
16 December 1993	Private Members' Bill on chiropractic introduced to the House of Commons
6 May 1994	Chiropractors Act passed
1996	Foundation for Integrated Medicine established (later renamed the Prince of Wales's Foundation for Integrated Health)
1997	Department of Health commissions Exeter University to produce report on CAM (Mills and Peacock, 1997)
1999	King's Fund announces £1 million grant to Foundation for Integrated Health
15 June 1999	Health Act 1999 passed
28 July 1999	House of Lords' Science and Technology Committee announces call for evidence on CAM
2000	Department of Health commissions Exeter University to produce 2nd report on CAM (Mills and Budd, 2000)
21 November 2000	House of Lords' Science and Technology Committee report published (House of Lords Select Committee on Science and Technology, 2000a)
March 2001	Government response to House of Lords published (Department of Health, 2001a)
1 January 2002	Acupuncture Regulatory Working Group (ARWG) and Herbal Medicine Regulatory Working Group (HMRWG) constituted
September 2003	ARWG and HMRWG publish reports (Acupuncture Regulatory Working Group, 2003; Herbal Medicine Regulatory Working Group, 2003)
March 2004	Department of Health consultation on statutory regulation of acupuncture and herbal medicine published (Department of Health, 2004a)
June 2004	Department of Health consultation closes
22 December 2004	Department of Health announces grant to Foundation for Integrated Health
February 2005	Department of Health consultation responses published (Department of Health, 2005b)
September 2005	Stone Report on the Future Voluntary Regulatory Structure for Complementary Health Care Professions commissioned by the Foundation for Integrated Health (Stone, 2005a)
May 2006	Foundation for Integrated Health launch consultation on federal voluntary regulation (Jack, 2006)

The government's decision to leave it to the professions to get their house in order was not universally endorsed. During debate in the House of Commons in 1993 Elizabeth Lynne MP (Liberal Democrat, Rochdale 1992-1997) urged the government to take a more proactive role in regulating CAM practitioners, saying:

I am a little concerned about the statement by Baroness Hooper, in a Lords debate on complementary medicine in May 1990, that an appropriate level of maturity is required on the part of the relevant professions before legislation would be considered. ...While I recognise the practical difficulties of proceeding along the path of regulation too soon, I hope that the Government will take a more active role to bring the various complementary therapies into a statutory framework (Hansard, 15 January 1993).

However, despite such appeals the state remained passive throughout much of the 1990s.

The Labour government elected in 1997 indicated it would not “depart from the previous government's line that it is for the therapies to organise themselves” (Bloomfield, 1997, para 54). In May 1999 Tessa Jowell MP, then Minister for Public Health, said that the government expected ‘aspiring professions’ to attain statutory self-regulation using the provisions of the Health Act 1999, as long as they “met certain conditions” (Department of Health, 2000b, p106).

Under the Health Act 1999 the Council for Professions Supplementary to Medicine (CPSM) was replaced by the Healthcare Professions Council (HPC) and its scope was expanded to enable it to register more health care practitioners.¹⁷ At the time the government envisaged that this would provide a route for CAM practitioners to gain statutory regulation. The HPC, as the CPSM had done before it, published explicit criteria which aspirant health care professions would have to meet in order to come under the Council (see Box 8.1). In a sense, the criteria embody the state's expectations of a profession.

¹⁷ The CPSM had a narrower remit having been established to regulate health care professionals working within the NHS.

Box 8.1 Criteria for a profession seeking regulation by the Healthcare Professions Council

Aspirant groups must:

1. Cover a discrete area of activity displaying some homogeneity
2. Apply a defined body of knowledge
3. Practise based on evidence of efficacy
4. Have at least one established professional body which accounts for a significant proportion of that occupational group
5. Operate a voluntary register
6. Have defined routes of entry to the profession
7. Have independently assessed entry qualifications
8. Have standards in relation to conduct, performance and ethics
9. Have Fitness to Practise procedures to enforce those standards
10. Be committed to continuous professional development

Source: (Health Professions Council, 2005)

The requirement that practise be based on evidence of efficacy posed a particular challenge to CAM (although professions such as music and art therapy, which the HPC regulates, do not have a strong evidence base either). In addition, the HPC was not keen to accept CAM practitioner groups. According to one Department official:

CAM therapies don't have enough in common with the professions that are regulated by the HPC. Certain criteria that the HPC set for entry into regulation just couldn't have been met. And the HPC approach is very much with a profession - 'come to us when you are ready' - the nature of complementary medicine means they need a lot of support and guidance (Sidwell, 2005, para 42).

The HPC is currently inundated with applications from aspirant professions including many new roles such as Anaesthesia Practitioner, Emergency Care Practitioner, Endoscopy Practitioner, Medical Care Practitioner and Surgical Care Practitioner (Department of Health, 2006c). Consequently the HPC has not been used to regulate CAM practitioners.

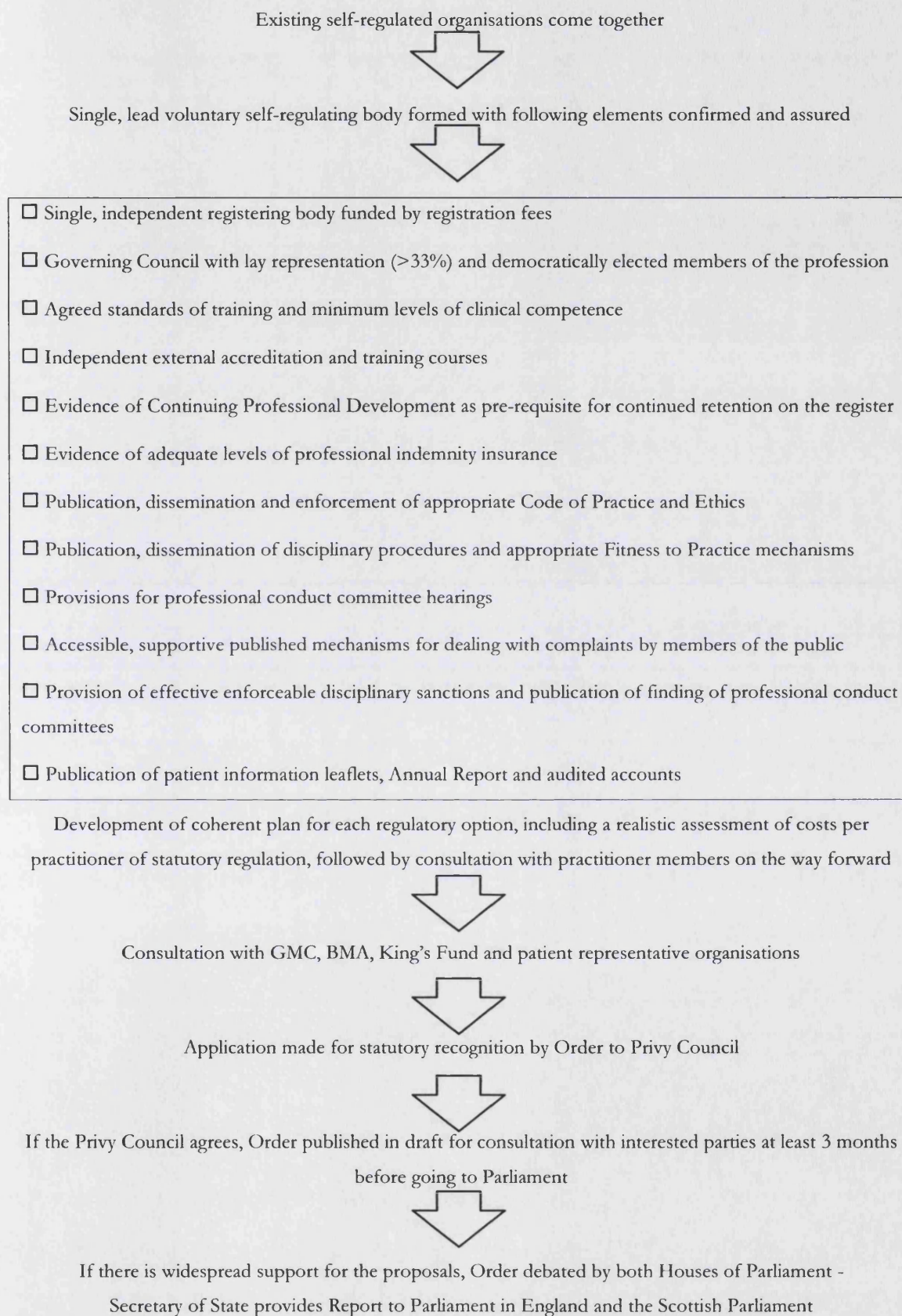
The government also simplified the process for establishing a new professional council under the provisions of the Health Act 1999. Practitioner groups would no longer require an Act of Parliament but could establish a council using a Section 60 Order. At the time, the Department of Health believed there was “scope for the larger professions to follow the Osteopaths and Chiropractors in gaining statutory self-regulation, and this would undoubtedly serve their professions well” (Department of Health, 2000b, p101). Budd and Mills (2000) at the University of Exeter were commissioned by the Department to produce an information pack that set out clearly the steps that practitioner groups would need to follow to gain statutory regulation (See Figure 8.4). A robust system of voluntary regulation was widely seen as a necessary condition to statutory regulation. The report made it clear that CAM practitioners would need to:

demonstrate they have made substantial progress in setting up voluntary arrangements to regulate the entire profession such as robust and transparent registering and regulatory systems; through formal consultation show that they have the support of the whole profession and other interested parties for statutory regulation (Budd and Mills, 2000, p6).

Similar views were espoused by those giving evidence to the House of Lords’ Select Committee. The Committee reported that, “There was general consensus among our witnesses that a good voluntary regulatory structure is needed for each CAM therapy before statutory regulation would be further considered” (House of Lords Select Committee on Science and Technology, 2000a, para 5.17).

Recognising that not all CAM professions would necessarily wish to pursue statutory regulation, the government presented a third option to CAM practitioners - to develop voluntary systems of professional self-regulation (Department of Health, 2000b). Sponsored by the Department of Health, Budd and Mills (2000) elaborated a model of voluntary self-regulation for CAM practitioners (Budd and Mills, 2000, p3). The Department left the choice to the practitioner groups as to whether to pursue a voluntary or statutory route (Department of Health, 2000b, p101).

Figure 8.4 Steps through regulation – flow chart and check list



Source: (Budd and Mills, 2000).

During this phase the state set the terms under which occupational groups could seek statutory regulation. It did this in a number of ways:

- establishing criteria which aspiring professions had to meet;
- broadening the scope of the Health Professions Council (HPC) and redefining its criteria for eligibility;
- simplifying the process for establishing a single council for each therapy;
- elaborating a model of robust voluntary self-regulation.

The Department of Health became more explicit about what it expected of CAM practitioners. The professionalisation activities of CAM practitioner groups (described more fully in the previous chapter) could therefore be reinterpreted as a response to the requirements of the state. Some stakeholders expected the government to take unilateral measures to regulate practitioners if practitioners did not “put their house in order” (Association of Community Health Councils for England and Wales, 1988, para 99) or to remove their common-law freedom to practise (Barnett, 2002, p36), nothing as dramatic occurred. In other words occupational groups professionalised in line with the state’s demands. It was left to CAM practitioner groups to organise themselves. There followed, however, a change in the state’s policy towards CAM practitioners, as we shall see in the following sections.

8.3 From professionalism to risk regulation

8.3.1 *Public interest in CAM*

In 1999 the House of Lords’ Select Committee on Science and Technology established a Sub-Committee to examine Complementary and Alternative Medicine. The Sub-Committee published its call for evidence in the summer of 1999. The interest generated by the Committee’s activities and its report appear to have prompted the government to take more decisive action to regulate CAM practitioners.

The widespread use of CAM therapies was a major driver behind the Lords’ Inquiry. The House of Lords’ Select Committee stated officially that, “It is this high level of public interest that has prompted our Inquiry” (House of Lords Select Committee on Science and Technology, 2000a). Lord Walton confirmed this in interview:

Now the reason for the Complementary and Alternative Medicine Select Committee Report was because the parent Select Committee on Science and Technology...recognized that a very large number of members of the population were consulting complementary and alternative medical practitioners and they felt at least that this whole issue needed to be explored and investigated in the interests of trying to bring some kind of regulatory mechanism to bear on the professions involved and also in order to protect the public (Walton, 2005).

It is likely that the issue was already on the government's agenda given the high levels of public interest and CAM's popularity. Yvette Cooper MP, Parliamentary Under Secretary of State for Public Health, said when giving evidence to the House of Lords' Committee:

We very much welcomed your Inquiry into this field. It is an area which has, I think, huge popularity for patients, but also where there is wide variation in understanding, in quality and in provision. I think that is rightly a matter of concern (Department of Health, 2000c, para 14).

The size and nature of the market made it difficult for the government to leave it unregulated. The Chief Executive of the British Acupuncture Council (BACc) remarked that "the government weren't going to let this world just paddle on, couldn't, it's too big" (O'Farrell, 2004, para 81) and "it can't stay as it is, people aren't going to let it stay as it is" (O'Farrell, 2004, para 85).

Department of Health officials thought that rising use of CAM therapies would fuel public demands for regulation. In evidence to the House of Lords the Department wrote:

...alongside the increase in popularity, will also come an increasing consumer awareness, and that patient themselves will be very keen to know; how is this kite marked; who is it regulated by and so on. I suspect the pressure will come in that direction as well (Department of Health, 2000b, para 1883).

The Medicines Control Agency (MCA) also expressed caution about the greater availability of herbal medicines in the UK, stating that:

...there has been a substantial growth in the traditional Chinese medicine which the MCA is very happy to see in the interests of public choice. However, there is no doubt that the safety and quality of these products is not always all that it should be (Department of Health, 2000d, para 87).

Richard Woodfield, Group Manager Herbal Policy at the Medicines and Healthcare products Regulatory Agency (MHRA) believed that increased demand had actually contributed to a reduction in quality. He said that:

with the growth of popularity of complementary and alternative medicine this had attracted people and interests who were not necessarily...well trained, experienced, qualified, depending on the area, and potentially there is downward pressure on quality (Woodfield, 2004, para 156).

According to the lead civil servant for CAM within the Department of Health, Ministers and officials received a steady stream of correspondence and questions on CAM. He reported that:

there's always been quite a heavy volume of correspondence on CAM...Ministerial post bags, routine correspondence,...quite a lot of briefing for debates, PQs [parliamentary questions], fairly heavy parliamentary postbag...quite routinely we'd be expected to brief for debates on Queen's speeches, [and] debates about health conditions where particular MPs would want to say... 'well what are you planning to do to use this or that therapy to help out in this case' (Brown, 2004, para 47).

The All Party Parliamentary Committee on complementary and alternative medicine (recently renamed the All Party Parliamentary Group for Integrated and Complementary Healthcare)¹⁸ has been active in keeping CAM on the agenda in parliament. A number of its current members served on the House of Lords' Sub-Committee on CAM including Lord Rea, Lord Colwyn and Earl Baldwin of Bewdley. David Tredinnick MP (Conservative, Bosworth 1987-present and the current Chair of the All Party Group) is perhaps the most vocal member on CAM issues currently sitting in the House of Commons. His frequent questions in the House prompted the former Secretary of State for Health Alan Milburn to joke:

I know that the hon. Gentleman has a certain regard for complementary therapies. I do not think that they are the talk of the pubs and the clubs in my constituency, but they may well be in his. One of the reasons why we gave the go-ahead for the additional £1 million [for research] was in the very real hope that he would not raise this issue at every single Question Time. Alas, my hopes have been dashed (Hansard, 29 April 2003).

¹⁸ In the 2006 Register of All-Party Groups the Group declared receipt of the following benefits: £5000 from the Foundation for Integrated Health, £3000 from the General Osteopathic Council, £1200 from the British Acupuncture Council, £1000 from European Herbal Practitioners Association and £1000 from Nelson Bach.

Such persistent questioning and debate in parliament, together with the direct lobbying of politicians by the public, no doubt contributed to a keen awareness within government of the level of public interest in CAM. This in turn contributed to a shift in attitude towards the regulation of CAM practitioners from one which allowed practitioners to choose whether they professionalised and at what pace, to one which actively encouraged practitioners to 'get their house in order'.

8.3.2 *Supporting the professionalisation of CAM practitioners*

During the proceedings of the Inquiry it is possible to trace a shift in the government's approach. The Chairman of the House of Lords' Committee, Lord Walton, was critical of the Department of Health:

It seems to me to be strange to place the initiative for the development on weak and under-resourced therapies when a lot can be done to help them, particularly by the department which has the brief of protecting the public? (Department of Health, 2000c, para 68).

Department officials responded by claiming that they were pro-active in supporting the development of voluntary regulation for CAM practitioners. Andy Smith, Branch Head in the Public Health Group, said that:

The Government have pointed the way forward for CAM professionals to take the initiative. The Government are being proactive in encouraging CAM professionals to take this initiative and have supported ongoing work at the University of Exeter. The department has been particularly active in the area of professional self-regulation (Department of Health, 2000d, para 68.).

At this time the government was supporting CAM practitioners to establish nationally agreed occupational standards. For example the Department of Health funded the University of Exeter to pilot a validation method for standards within reflexology (Mills and Budd, 2000). Healthwork UK (the National Training Organisation for the health sector until 2002) was asked to work with a wider range of CAM practitioners to develop outcome based standards of professional competence.¹⁹ The Department also played a role in shaping the development of voluntary systems of self-regulation. Between 1999 and 2004 the Foundation for Integrated Health were funded through a grant from the King's Fund to support the development of regulation among CAM practitioners. The Department was represented on the Foundation's Regulation Core Group and had influence over which therapies received grant monies. The Department of Health "were

¹⁹ Skills for Health took over responsibility for this work in 2004.

involved in the decision-making process about who should get what, ensuring the money was going to professions where they had evolved with their structures, where they were showing clear accountability” (Sidwell, 2005, para 86).

Frances Blunden, Principal Policy Adviser at the Consumers Association, believed the government needed to take a more proactive stance, particularly as the practitioners had reached an impasse:

you do have to wait a bit but there comes a point in time I think where...it looks as if often that they are never ever going to agree to come to a common scheme, so there is actually something about saying, right you've got to do this and to give that as a catalyst (Blunden, 2004, para 79).

She went on to argue that if the state wanted to see these groups regulated it would need to act as a “promoter and catalyst” in bringing the profession together (Blunden, 2004, para 107).

In the final evidence session held by the House of Lords’ Select Committee in October 2000 Yvette Cooper MP, the Parliamentary Under Secretary of State for Public Health, admitted that the passive approach was untenable. She conceded that the state needed to be pro-active in the process of professionalisation, saying that:

...to take the approach which says that you will just wait for the professions to take their time and to become sufficiently mature to provide a self-regulatory framework that we will then make statutory at some point down the line, where there are public health issues and safety issues at stake, is perhaps not a position we can hold; because should there be professions where they are not making progress or they are not going to get there, then perhaps we have a responsibility to engage in that process as well (Department of Health, 2000c, para 1880).

She concluded that “it might be sensible to set out a timescale and also to set out a consultation paper” (Department of Health, 2000c, para 1881). The Minister was questioned as to whether the state might impose regulation in such cases. Earl Baldwin of Bewdley quizzed her saying:

That sounds almost from your side as if you are setting out those professions where you think there might be a risk to the public, and going to the professions and saying, “I think you must have a statutory rule”. Is that what you are saying? (Department of Health, 2000c, para 1881).

In reply the Minister made it clear that the government supported the statutory regulation of acupuncture and herbal medicine because of “a potential for harm” (Department of Health, 2000c, para 1881).

8.3.3 *The potential for harm*

Department of Health officials began to distinguish between therapies according to their level of risk at the time of the Lords’ Inquiry. One official giving oral evidence to the House of Lords’ Committee admitted:

There is a wide range of complementary and alternative therapies and the message about self-regulation is for all of them. But it may be of particular relevance to those which are more widely used and those which have the potential to cause harm (Department of Health, 2000d, para 2).

Sir Liam Donaldson, the Chief Medical Officer focused on the risks posed by unregulated CAM practitioners, though he played down the magnitude of the problem:

I do not perceive there is any general serious threat to the public health as a result of the present regulatory position, but I do think it is important that we start to move forward and ensure...that practice...is regulated (Department of Health, 2000c, para 1865).

‘Public protection’, or its synonyms such as ‘public safety’ or ‘safeguarding public health’, were the most frequently cited justifications for regulation of CAM practitioners in the data. There was a wide range of risks associated with the unregulated practice of CAM. A distinction can be made between direct risks associated with the mode of intervention, e.g. physical manipulation, ingestive remedies, etc, and those associated with the lack of appropriate referral (Stone and Matthews, 1996). The main types of direct risk mentioned were concerned with (i) toxicity or contamination - the adulteration of therapeutic products with poisonous or otherwise harmful or toxic substances (e.g. steroids in topical herbal ointments); (ii) potency - the concentration and strength of effect of therapeutic products which may in some patients produce adverse outcomes (e.g. liver disease caused by ingestion of herb); (iii) invasiveness - the extent to which the treatment or substance enters the body either through skin penetration or oral ingestion (e.g. lung collapse due to incorrect insertion of needles); (iv) infection – the transfer or introduction of infectious agents into the body (e.g. hepatitis or HIV transmission from unclean acupuncture needles); (v) manipulation – direct injury as a consequence of the application of manipulative techniques (e.g. from spinal manipulation); and (vi) psychological damage –

emotional harm arising from abusive or distressing psychotherapeutic relationships (e.g. sexual assault by hypnotherapists).

The House of Lords' report defined an indirect or extrinsic risk as "the risk of omission of conventional medical treatment" (House of Lords Select Committee on Science and Technology, 2000a, para 5.54). The following factors were identified in the data as being associated with indirect risks: (i) CAM therapies that had an alternative clinical system – fears of misdiagnosis, inappropriate treatment and lack of appropriate referral; (ii) lack of skills of a CAM practitioner - words such as 'incompetent', 'unqualified' or 'untrained' were used to describe these dangerous practitioners; and (iii) unethical conduct – including abuse, overcharging, false or fraudulent claims. Regulation may seek to minimise any or all of these risks.

The House of Lords' report made a number of recommendations in each of the areas it covered: evidence, regulation, professional education and training, research, information and delivery. In relation to regulation it recommended that each therapy should establish a single, unified regulatory or professional body, that acupuncture and herbal medicine seek statutory regulation under the Health Act 1999 and that non-medical homeopaths consider doing so in future, that existing health care regulators develop guidelines on competency and training for their members, and that conventional health care practitioners should be trained to standards comparable to those set out for non-medical CAM therapists (for a complete list of recommendations see Appendix 6).

The Lords' recommendation that acupuncture and herbal medicine should be brought under statutory self-regulation were based on three criteria: "first, the possible risk to the public from poor practice; second, a pre-existing robust voluntary regulatory system; and third, the presence of a credible evidence base" (House of Lords Select Committee on Science and Technology, 2000a, para V). The House of Lords' Select Committee added a caveat to these criteria suggesting that lack of professional development should not stop statutory regulation proceeding if there is a demonstrable risk. In their report they stated that:

...if a therapy posed significant intrinsic risks and had a poor voluntary regulatory structure, it might be worth the Department of Health putting pressure on that therapy to come under a statutory regulatory system (House of Lords Select Committee on Science and Technology, 2000a, para 5.54).

The government responded quickly to the Report and accepted the vast majority of the Lords' recommendations. In their response to the Lords' recommendations the

government recognised that many of the CAM practitioner groups had made progress with professionalisation but that there was a need for the process to be accelerated. The government's response stated:

Many of the CAM professions have begun making the changes they need to secure a more lasting place in broader health provision. But those changes must now be driven forward more decisively. All the professions need to adapt and improve and, in doing so, they must work together more (Department of Health, 2001a, para 15).

The government's perception of the growth in use of CAM therapies and their associated risks were the main determinants of actions that followed the House of Lords' Inquiry. The shift to a more proactive stance in relation to CAM practitioners appears to stem from the government's concern to protect public health and reduce risks faced by patients seeking care from unregulated (and inadequately trained) practitioners. This reflected a wider focus on safety and quality of health care at the time (Department of Health, 1998; Department of Health, 2000a). In the Department of Health's proposal for the statutory regulation of acupuncture and herbal medicine, the introduction states:

This Government is committed to increasing public and patient protection and improving quality in all healthcare settings. As interest in complementary medicine grows, so too must our focus on public safety and ensuring effective standards (Department of Health, 2004a, para 8).

These ideas about risk also reflect wider trends in regulation where reduction of risk has become an objective of regulation in and of itself (Hood, Rothstein et al., 2001). More recently the term 'risk regulation' has been used to describe regulation that is proportionate to the risks posed by the activity (see below).

8.4 Better regulation

There was frequent mention in the data of the need for regulation to be 'proportionate', 'flexible' or 'appropriate'. These concepts derive from the work of the Better Regulation Taskforce²⁰ whose objectives are to cut red tape and reduce the amount of 'unnecessary' regulation. For example the Department of Health in their response to the House of Lords' Report stated that:

²⁰ The Better Regulation Task Force was established by the government to recommend ways of reducing the administrative burden on businesses and organisations and to ensure regulation was necessary and proportionate. All new policies undergo regulatory impact assessment. The Task Force was succeeded by the Better Regulation Commission following an announcement in the 2005 budget.

The Government's overall policy towards better regulation is that it should be both proportionate and effective. In other words, the regulation should give customers adequate protection, without stifling the commercial services they want (Department of Health, 2001a, para 12).

The government, keen to ensure that the benefits of regulation outweigh the costs, has adopted a more conservative approach, preferring voluntary regulation to statutory regulation for CAM practitioners. The government's approach to better regulation was picked up by the Manager of the Regulation Programme at the Foundation for Integrated Health who said "it's not necessary to have SSR [statutory self-regulation] for all the groups...it's the Better Regulation Task Force idea...don't try and crack a nut with a sledgehammer" (Jack, 2004, para 106).

The Human Resources Directorate (HRD), which took over responsibility for regulation of CAM practitioners within the Department of Health in 2003, were "not heavily into voluntary regulation" but welcomed the Foundation's work in this area (Brown, 2004, para 251). Indeed, they had no experience of it, having previously only dealt with existing statutory regulators. On the other hand they did not wish to see a proliferation of statutory regulators. One official indicated that:

[civil servants] recognise that there are various groups in healthcare that don't really on the face of it make a strong case for statutory self-regulation. There's no strong wish to proliferate statutory self-regulation across the Department (Brown, 2004, para 251).

Furthermore, there were reports that the officials had "some concerns about the fact that there are more regulatory bodies up and coming and ...they don't want to see too many of these smaller regulatory bodies" (Jack, 2004, para 110).

Recognising that the majority of CAM practitioners operate as small businesses in the private sector, the government was concerned that regulations might stifle economic activity. Julie Stone, Deputy Director at the Council for Healthcare Regulatory Excellence (CHRE), explained that "the government views regulation as an economic burden". From their perspective "Professional regulation, whether it costs the government money or not,... may be putting a brake on competition or creating a cartel" (Stone, 2005b, para 112). Consequently new statutory measures are only to be introduced where there is a strong public interest argument and the benefits outweigh the costs. Yet the professions cannot understand why the government is interested in the costs of regulation when the registrants pay for regulation themselves (Stone, 2005b, para 110).

Influenced by wider government concerns about the burden of regulation, officials at the Department of Health wanted “to minimise any new groups”, but that meant “putting in additional work to produce credible voluntary self-regulation” (Brown, 2004, para 251). The government decided to support the establishment of single voluntary registers in preference to introducing legislation to statutorily regulate each of the therapies (beyond that to which they were committed).

In 2005 the Department of Health announced a three-year grant of £900,000 to support the continuation of the Foundation’s Regulation Programme. Steve Catling, Head of Professional Standards and Pensions at the Department of Health, was quoted to say:

It is increasingly vital that people trust both healthcare practitioners and the bodies that train, licence and regulate them, and the Department of Health is keen to support this work through a three-year fund (Prince of Wales's Foundation for Integrated Health, 2004).

Whereas previously the development of voluntary regulation had been seen as a step on the path to statutory regulation, the Department was now supporting robust systems of voluntary regulation as an alternative to statutory regulation.

The ideas of better regulation also favour larger blocks of professions working together. The government’s proposals for an umbrella CAM Council to regulate acupuncturists and herbalists indicate support for federal and collaborative models of regulation. The Department stated in its proposals for the regulation of acupuncture and herbal medicine that:

wherever possible, the Council's statutory committees should take a multi-professional approach to their work. The experience of other statutory regulatory bodies demonstrates that the majority of issues relating to education, registration, health, discipline and ethics are common across healthcare professions (Department of Health, 2004a, para 121).

The latter observation might also have suggested that the government would propose a merging of functions among all health care professional regulators. Although the proposals contained in the Department’s review of non-medical health care professional regulation support a shift in government policy towards collaborative regulation in an effort to ‘reduce the burden of regulation’ (Department of Health, 2006c), it does not appear that anything as radical as an umbrella council or federal regulator will be proposed for the statutory sector. However, a federal structure is proposed for the voluntary regulation of CAM practitioners (Stone, 2005a).

The application of the concept of better regulation to the health sector is relatively recent (Dixon, 2006). Terms such as ‘proportionate’ have only entered policy debates about the regulation of CAM practitioners since 2001. However, concerns about safeguarding consumer choice have been around for much longer.

8.5 Consumer choice

Successive governments have been cautious about introducing regulations in the CAM market that would restrict consumer choice. The Conservative government spoke about balancing ‘consumer protection’ and ‘freedom of choice’ (Trumpington, 1987, p337). They believed that consumers:

want to be protected from unsafe and ineffective medicines...from the charlatan and from fraudulent claims...it is only if we can be protected from such excesses that it is possible for us to retain a genuine freedom of choice (Trumpington, 1987, p336).

In 1987 Tony Newton MP, Minister of Health, in a speech to members of the Natural Therapeutic and Osteopathic Society declared that “The government firmly believes in the public’s right of choice and has no wish to restrict the practice of therapies which many people undoubtedly find useful” (Association of Community Health Councils for England and Wales, 1988).

Similar views were expressed by the 1997 Labour government in the preface to the Department of Health’s evidence to the House of Lords’ Sub-Committee which stated that, “In matters of regulation, it is the Government’s intention to maintain freedom of choice whilst ensuring that appropriate safeguards are in place” (Department of Health, 2000b, para 9). It went on to say that “In relation to the regulation of CAM products, the Government does not wish to limit consumer choice, but at the same time it wants to encourage suppliers to adopt the highest standards” (Department of Health, 2000b, para 12).

Concern about consumer choice has been particularly prominent in relation to product regulation. In giving evidence to the House of Lords’ an official from the Medicines Control Agency said:

The UK has taken the lead in urging the need for a proper discussion in Europe to try to agree a common approach, if at all possible in the interests of promoting an effective regulatory regime which provides a level playing field for companies and general certainty for business...Our overall objective in this is to balance consumer safety and choice (Department of Health, 2000d, para 91).

The Group Manager for Herbal Policy at the MHRA said there were three main justifications for regulation of herbal medicine - public health, informed consumer choice and a more efficient market that supports responsible manufacturers and practitioners - but claimed “public health is... number one” (Woodfield, 2004, para 48).

The Department of Health wrote, “Potentially, this [the EU directive on traditional medicinal products] could provide a legally secure regime effectively balancing consumer choice and public safety” (Department of Health, 2001a, para 69). During debate in the House of Lords on the CAM report, Lord Burlison stated for the government “The aim is to provide a framework for the effective regulation of traditionally used medicines, including herbal remedies, balancing public safety and consumer choice” (Hansard, 29 March 2001). Speaking critically of the government’s proposals for licensing of herbal medicines, David Tredinnick MP said they would “result in restriction of choice, my party stands for choice, not restriction and it will prove damaging to the industry as a whole” (Hansard, 20 January 2003).

The House of Lords’ Sub-Committee was not convinced by arguments that statutory regulation of CAM practitioners would restrict consumer choice (House of Lords Select Committee on Science and Technology, 2000a, para 572). The Committee argued that:

Statutory regulation could even have the opposite effect by giving consumers the confidence to consult practitioners whom they might not otherwise consult due to concerns about regulation (House of Lords Select Committee on Science and Technology, 2000a, para 573).

In 2004, Dr. John Reid MP, then Secretary of State for Health, used this argument, “We need the regulation of that sector [CAM] because then we can extend patients choice on using elements of it” (Hansard, 23 March 2004). Regulation in other markets is often designed to correct market failures and by doing so is expected to increase consumer choice and confidence.

As this section has demonstrated, policymakers perceive there to be a tension between regulation designed to protect patients from unsafe or harmful practice by CAM practitioners and a consumer’s right to seek care from whomever they choose.

8.6 The state’s role in the regulation of CAM practitioners

The previous sections identified three different phases in the state’s interest in CAM practitioner regulation. In the beginning the state encouraged professionalisation but did not force it upon practitioners, it then acted more decisively to reduce risks to public health, and finally, concerned to minimise excessive regulation, it now seeks to ensure any

regulation is proportionate. The following section considers the extent to which the state's actions can explain the regulation of the five CAM therapies examined in this study.

8.6.1 Osteopathy and chiropractic

Osteopaths and chiropractors pursued statutory regulation at a time when the government took a passive approach towards the regulation of CAM practitioners. The government criteria set out between 1985 and 1987 shaped the activities of osteopaths and chiropractors. Practitioner groups believed that if they could prove they met the criteria the state would reward them with statutory regulation. Osteopathy made more progress towards meeting the criteria than other CAM therapies and was “closest to getting its own house in order” (Association of Community Health Councils for England and Wales, 1988, para 67). The chiropractors were not far behind.

The King's Fund established a Working Party on Osteopathy in 1989 in order to make recommendations about the regulation of the profession and to produce a draft Bill. When approached by the Fund, the Department gave a “strong indication” that they would give serious consideration to a Bill. And that “...it would be helpful for somebody like the King's Fund to take an interest” (Maxwell, 2005). After the publication of the report of the King's Fund Working Party on Osteopathy there were “extensive discussions with the Department of Health” involving “several senior civil servants in the Department of Health and also Ministers”, at the end of which “they recognised the validity of the case” (Walton, 2005). Thus there was tacit government support for the efforts of the osteopaths to achieve statutory recognition.

When the Osteopath's Bill ran out of parliamentary time because the general election was called for 9th April 1992, Baroness Cumberlege, Parliamentary Under-Secretary of State for Health in the Lords 1992-1997, gave an undertaking that the government would do something in a new parliament (Maxwell, 2005). In the end Malcolm Moss MP took up the Osteopaths Bill in the House of Commons.

The Fund set up a Working Party on Chiropractic in 1992 to draft the Chiropractors Bill. By 1993 the chiropractors were able to demonstrate that they had the support of the majority of practitioners and the medical profession, and that they had developed robust systems of voluntary regulation. The recommendations of the Working Party made a public interest argument for statutory regulation (Hutchinson, 1994). During the debate of the Osteopaths Bill in 1993, David Tredinnick MP declared chiropractors had “put their house in order, as requested by the Department” and called for them to be statutorily regulated after the osteopaths (Hansard, 15 January 1993).

There are direct risks associated with both osteopathy and chiropractic, particularly spinal manipulation or manipulating someone with malignant disease. In general these risks are seen to result from poor or unskilled practice. David Lidington MP, who introduced the Chiropractors Bill in the House of Commons, described the dangers of chiropractic during debate in the House of Commons:

...there is potential, in untrained hands, to do a great deal of harm. The manipulation of necks and backs could be lethal without the proper degree of skill. Even relatively minor adjustments to limbs, if attempted in ignorance, could result in severe damage (Hansard, 15 January 1993).

Although risk was mentioned it was not central to the debate or the decision to pass the Bill.

Both the Osteopaths Act 1993 and the Chiropractors Act 1994 passed with the support of government and opposition MPs. The osteopaths and chiropractors had met the criteria set out by the government and their efforts were rewarded with parliamentary support for the Private Members' Bills.

8.6.2 *Acupuncturists and herbalists*

During the late 1990s when the herbalists were keen to gain statutory regulation they were given a document by the Department of Health advising them on what was required. The state set out the path that they expected the herbalists to follow. In response the European Herbal Practitioners Association (EHPA) were "busy producing all the documents that they have suggested to us we should put in place....[and] putting ourselves in order in such a way that we can make an application for statutory self-regulation" (European Herbal Practitioners Association, 2000b, para 714). It is likely they would have applied under the Health Act 1999 either for a single statutory council or to join the newly established HPC (European Herbal Practitioners Association, 2000a, para 20). In fact events overtook them.

Instances of adverse events as a result of the ingestion of powerful herbs or herbs contaminated with toxic substances were widely publicised both in the UK and internationally, and were seen as credible because of evidence from the MCA and other international regulators. There was a general consensus on the potential harm of herbal medicines due to their toxicity. For example, the Academy of Medical Sciences claimed "There is indeed substantial evidence of people having come to serious harm, having had renal failure, liver disease and having been given steroids in unregulated amounts" (Academy of Medical Sciences, 2000, para 1424). Even the Chairman of the EHPA was

“concerned that there should be no toxicity and that there should be adequate reporting of problems” (European Herbal Practitioners Association, 2000b, para 731).

The UK government successfully lobbied for an EU Directive on Traditional Medicinal Products (2004/24/EC) which introduced quality and safety standards for manufactured herbal products, but which left the regulation of herbal medicine prepared and dispensed by practitioners untouched (Woodfield, 2004, para 36). The MHRA considered that, overall, reform to bring in effective regulation of herbal medicines depended on consistent action in three areas: the introduction of the traditional herbal registration scheme for manufactures over-the-counter products, reform of the Section 12(1) regime (where unlicensed herbal medicines are made up by herbal practitioners), and statutory regulation of the herbal medicine profession (Woodfield, 2004). The fact that the MHRA continues to find evidence of risk to public health from herbal medicines gives greater impetus to the introduction of statutory regulation for herbalists.

The recommendations of the House of Lords’ Committee and the response of the Department of Health meant that herbalists, together with acupuncturists, became caught up in a much more proactive process facilitated by state officials. The Lords’ Sub-Committee was clear that herbal medicine had direct risks associated with it which justified statutory regulation.

The risk of harm from acupuncture was much more circumstantial. The direct risks associated with acupuncture concerned its invasive nature and the potential for transmitting infection. The piercing of the skin with acupuncture needles can transmit blood borne disease or introduce infection if proper standards of hygiene are not observed. One or two witnesses giving evidence to the Lords mentioned the possibility of lung punctures. However, there was a lack of any systematic data on adverse events. Cases where acupuncture needles had caused a lung puncture were cited by Lord Walton as one of the reasons why the Committee recommended the regulation of acupuncture. The Committee were determined that protection of the public and defining standards of training and care should be principal concerns (Walton, 2005, para 79). During discussions within the Acupuncture Regulatory Working Group (ARWG) medical acupuncturists apparently claimed to have seen “patients who had been wrongly treated and had problems of infection, problems of damage to nerves and all that sort of thing” (Chan, 2005, para 44). The Chief Executive of the British Medical Acupuncture Society (BMAS) played down the risks associated with acupuncture:

Acupuncture is pretty safe. We know about the common adverse events. The serious adverse events are extremely rare, vanishingly rare. ...I believe the best use of acupuncture isn't to restrict its use to people who just do acupuncture. Because frankly acupuncture isn't a very powerful technique relative to modern medicine. ...in general powerful techniques come with powerful side effects and you don't have powerful side effects with acupuncture. It's very good in a few areas and in other areas it has very mild effects as it appears from all the data (Cummings, 2005, para 90).

This position may reflect the timing of the interview. The BMAS were attempting to down play the risks of acupuncture by contrasting them with the risks of orthodox medicine. They hoped by doing so that government proposals to regulate acupuncturists would not result in stringent regulations and training requirements being imposed on its members. Doctors and other statutory professionals wanted to be able to continue to practise acupuncture without lengthy formal training.

The Department of Health accepted the case for statutory regulation of acupuncture and herbal medicine on the basis of their level of professional development and their risks (Department of Health, 2001a, para 51). Yet despite this emphasis on risk regulation the Chief Executive of the BAaC, representing non-medical acupuncturists, believed that they were being encouraged to move to statutory self-regulation because they were “further advanced” (O'Farrell, 2004, para 191). The government, together with the Foundation for Integrated Health, supported the establishment of independently chaired regulatory working groups to facilitate the process of consensus building to develop proposals for regulation.

The ARWG was established in 2002 and met under the chairmanship of Lord Chan of Oxton for a period of a year. Representatives from four main groups were involved: the BAaC, the British Academy of Western Acupuncture (BAWA), the BMAS and the Acupuncture Association of Chartered Physiotherapists (AACP) (see Appendix 7 for a full list of members). The Terms of Reference for the ARWG were to produce a report which: a) examines the options to achieve successful statutory regulation of the acupuncture profession as a whole; and b) makes recommendations that will form the basis for wider consultation by the Government and subsequently for the legislation that will enable the statutory regulation of the acupuncture profession.

The Department had already been engaged with the acupuncturists prior to the establishment of the ARWG:

We spent quite a bit of time working with different organisations to promote that process of coming together, setting up the organisation and some of the other areas and issues that professions need to consider when they are going down that track: it is not a simple process and it can take considerable time to do so (Department of Health, 2000c).

During 2001 the Department of Health worked with acupuncture groups to determine “how to have a proper discussion about regulation” (Chan, 2005). But the discussions “were constantly deadlocked...there were continual re-discussions of points such as terminology...and the...importance of the philosophical background” (Chan, 2005, para 8). This fuelled a growing sense of frustration in the Department of Health. As one official admitted “frankly over time it just wasn’t possible to make any lasting progress at all with any of these groups until they had got together on a semi-formal basis with an independent chairman and lay members” (Brown, 2004, para 245).

The Herbal Medicine Regulatory Working Group (HMRWG) established in 2002 was made up of representatives from a range of herbal medicine traditions (see Appendix 7 for a full list of members) and met under the chairmanship of Michael Pittilo, Vice Chancellor of the University of Hertfordshire at the time. It had broader terms of reference:

- produce a report which examines the options for achieving the successful statutory regulation of the herbal medicine profession as a whole, and makes recommendations which will form the basis for a wider consultation by the Government and subsequently for the legislation that will enable the statutory regulation of the herbal medicine profession;
- in the light of these recommendations for the statutory regulation of the profession and the current Medicines and Healthcare products Regulatory Agency (formerly the Medicines Control Agency) review of Section 12(1) of the Medicines Act 1968, make recommendations for assuring the safety and quality of herbal remedies supplied under Section 12(1).

The difference from earlier discussions was that the groups were given external impetus by the government’s involvement and that of an independent chair and lay members. This ensured that professional differences were minimised and greater efforts were made to reach a consensus on how statutory self-regulation should operate. Both the HMRWG and the ARWG were resourced by the Department – including support for the appointment of an external chair to each group, hiring meeting venues, and providing catering and other secretarial support. In this regard, compared to other health care professionals, “CAM has had a very good deal” (Sidwell, 2005).

The process was by no means smooth, with continued conflict between practitioners, but the Department of Health continued to play an active role. Officials worked behind the scenes “...encouraging and supporting the acupuncturists to talk to their TCM [traditional Chinese medicine] colleagues” (Sidwell, 2005). Having made a public commitment to introduce statutory self-regulation for acupuncture and herbal medicine the Department were reluctant to give up on the process - “it would have been quite difficult to walk away” (Sidwell, 2005, para 103). One official sharing her personal reflections said:

I think it is very difficult with CAM because the Department gave CAM more right from the beginning. It gave it the two working groups, the support to get through that stage of the process and...it would have been quite difficult for the Department having put in that support to then withdraw (Sidwell, 2005, para 101).

The impetus within the Department was evident to leaders of the practitioner groups. For example Michael O’Farrell, the Chief Executive of the BAaC, commented that:

the momentum has continued since then [the House of Lords’ report], I mean there has been no let up, there’s been changes in personnel within the DoH, continuous changes, but the momentum around it has not changed at all (O’Farrell, 2004).

Apparently O’Farrell was also “very quick to remind the profession that the Department has a lot of other much greater priorities and if they [the acupuncturists] didn’t get their house in order it would eventually stop trying” (Sidwell, 2005). Practitioners’ leaders also recognised that the level of support from government gave them a unique opportunity to achieve statutory regulation. According to one Department official:

the people at the top of the profession were always very aware of and very appreciative of [the support] and had to remind the more difficult practitioner representatives that this was a chance that other professions don’t get (Sidwell, 2005, para 101).

8.6.3 Homeopaths

In contrast to herbal medicine, homeopathic medicines were seen to be so dilute as to render any direct risks negligible. Conventional health care practitioners found it inconceivable that homeopathic products had a pharmacological effect (Academy of Medical Sciences, 2000, para 1409). The high dilutions meant that it was impossible for them to cause harm, but also impossible to do any good either. The Chairman of the House of Lords’ Sub-Committee admitted that members of the committee had “great difficulty in understanding how and if homeopathy works” (Academy of Medical Sciences, 2000, para 1412). The MHRA were clear it posed little risk; “...homeopathic

medicines...are very much at the safe end of the spectrum; they are very dilute” (Department of Health, 2000d). The Society of Homeopaths played down the risks, possibly because they were not keen to be statutorily regulated (see previous chapter). They claimed “The level of intrinsic risk from the consultation process and the potentised medicines used in homoeopathy is extremely small by comparison [with osteopathy and chiropractic]” (Society of Homeopaths, 2000a, p 218). Medical homeopaths claimed that homeopathy did pose a “significant overall total risk”, but this resulted from indirect risks rather than direct risks of the treatments (see below) (Faculty of Homeopathy, Homeopathic Trust and British Homoeopathic Association, 2000, para 646).

There was much confusion over how to apply the criteria of direct risk of harm to homeopathy. For example, a Department of Health official believed it should have been classified with herbals and acupuncture as “invasive” because it is ingested (Sidwell, 2005, para 21). As their report shows, the House of Lords’ Committee recognised that “homeopathy was not such a clear case for statutory regulation because homeopathic medicines weren’t dangerous by normal definitions”. However, after weighing other factors, they were able to recommend that, “perhaps there are good reasons why...in due course homeopathy...ought to have state regulation” (Brown, 2004, para 343). Other reasons why this recommendation was made are explored in the following chapter.

The Committee’s recommendation that homeopathy should be brought under statutory regulation at some point was largely based on concerns that patients were not getting conventional treatment. Such concerns were emphasised by the medical homeopaths. Peter Fisher Vice President of the Faculty and Clinical Director Royal London Homeopathic Hospital said that:

The total risk is quite great because of questions such as misdiagnosis, or people being discouraged from having effective conventional treatments or being told to stop them abruptly...The high total risk is related to the fact that it is a therapy that can be applied in a lot of different situations (Faculty of Homeopathy, Homeopathic Trust and British Homoeopathic Association, 2000, para 646).

The House of Lords’ report concluded that,

While the practice of homeopathy may itself be free from risk, it does create an opportunity for diverting conventional diagnosis and treatment away from patients with conditions where conventional treatment is well-established, as some patients seem to see it as offering a complete alternative to conventional medicine. Such attitudes mean that homeopaths are in a position of great responsibility. It is imperative that there is a way of ensuring that this position is handled professionally, that all homeopaths are registered, that they know the limits of their competence, and that there are disciplinary procedures with real teeth in place (House of Lords Select Committee on Science and Technology, 2000a).

The Committee had no evidence of the intrinsic risk of homeopathy. In fact it seems they were convinced that the dilutions rendered it harmless (and ineffective), but were concerned that patients who attended homeopaths might not receive the appropriate allopathic treatment.

Consequently, the homeopathy profession's efforts have been focused on establishing a robust system of voluntary regulation (as a precursor to possible statutory regulation in future). The work of the Council for Organisations Registering Homeopaths (CORH) has focused closely on adhering to the guidance given to groups developing voluntary regulation. They are working to establish a single register, an accreditation board, and to agree a code of ethics and practice. These efforts have been shaped in part by the model of voluntary regulation set out by Budd and Mills (2000) and reproduced in the House of Lords' Committee Report. The homeopaths have also been given further impetus and support through the Foundation's Regulation Programme, funded initially by the King's Fund and latterly by the Department of Health. They have also been supported by Skills for Health in the development of national occupational standards.

Recent changes in the government's approach to regulation suggest that despite the House of Lords' recommendation that homeopaths might at some point become statutorily regulated, this is now unlikely. Given the level of risk posed by homeopaths they would likely fail any test of proportionality. Instead, the government is actively subsidising the establishment of a robust system of voluntary regulation.

8.7 Discussion

The preceding analysis has shown that the state's policy towards CAM practitioners changed over time. In the first phase the state decided to regulate CAM practitioners in response to professional demands in cases where the practitioners could demonstrate they had a body of knowledge supported by externally validated training courses, had a robust system of voluntary regulation and were unified. From the mid-1980s to the late 1990s

statutory regulation was viewed as a professional privilege, granted to those occupations who had successfully organised themselves and mobilised support from the medical profession and their members. The role of government at this time was largely passive, setting the criteria which aspiring professions had to meet.

The government included in the Health Act 1999 new provisions which it hoped would provide easier mechanisms for CAM practitioners to gain statutory regulation. However, the route of joining the HPC was based on a set of criteria which no CAM therapies were able to meet. CAM practitioner groups were encouraged to get 'their house in order' and to establish voluntary systems of regulation as a precursor to statutory self-regulation. The level of disagreement and fragmentation within therapies meant little progress was made. The passive approach allowed practitioners to draw their own boundaries between different traditions or factions and to professionalise at their own pace.

In the second phase the state's concern was to protect the public from risks to health, in cases where there was direct risk of harm. The increasing use of CAM services by the public, together with growing concerns about risks to public health, prompted the government to become more proactive in facilitating the regulatory process. The shift to a risk-based approach with a primary objective of public protection meant the government had to decide which therapeutic practices posed a risk. Risk was used as a criteria for determining which therapies should be statutorily regulated. The decision to regulate largely depended on the definition of risk adopted rather than evidence of adverse outcomes. The Department of Health, following the recommendations of the House of Lords' Sub-Committee, singled out acupuncture and herbal medicine (including traditional Chinese medicine and Ayurveda) for statutory regulation because they believed they posed a direct physical risk. The state helped the professions to move ahead more rapidly with preparations for statutory regulation.

In the final phase the state will only regulate if the benefits outweighed the costs and in a way that minimizes the regulatory burden on businesses and providers of services. Concerns about over-regulation and ideas about better regulation mean the government is more cautious about introducing further statutory regulation of CAM practitioners. Instead it is supporting other CAM practitioner groups to develop more robust systems of voluntary regulation. It also favours developing federal or collaborative models of regulation in which the costs of regulation can be shared (see Chapter 10).

Consumer choice was a strong countervailing argument to regulation. Concerns that heavy-handed regulation can place limits on consumer choice have been present throughout the debates examined here. The finding that there is a tension between the government's duty

to protect the public and its obligation to respond to consumer pressure is largely consistent with other research (Kelner, Wellman et al., 2004b).

In general, the findings here suggest that the state was largely passive at the time osteopathy and chiropractic were regulated. These professions were rewarded with statutory regulation because they met the criteria set by the state. In relation to herbal medicine and acupuncture the state introduced statutory regulation in response to concerns about risk, and actively encouraged the formation of unified professional groups. Homeopathy was not believed to pose any direct risks so was encouraged to develop a single voluntary register. The current concerns with better regulation mean the state is now encouraging other CAM practitioners to form a voluntary federal regulator. The state is unlikely to regulate further CAM practitioners beyond acupuncture and herbal medicine.

The analysis using demand theories of professionalisation in the previous chapter went some way towards explaining why some groups of CAM practitioners obtained statutory recognition while others did not. The analysis in this chapter has highlighted the important role the state plays in shaping the context in which professions develop. The supply theories of professionalisation have provided a more coherent understanding of why some CAM practitioners achieved statutory regulation and others did not.

One of the shortcomings of the supply theories of professionalisation is that the state is treated as a single entity. There is no recognition that the state is made up of numerous stakeholders, e.g. elected politicians, Ministers, officials and civil servants, and peers, all of whom may have different and potentially competing interests. Supply theories also portray occupational groups as passive, with little or no autonomy to oppose the state's will for them or to pervert the interests of the state. The next chapter attempts to bring together the analysis of the state and of practitioner groups into a more complete analytical framework. It adopts a more heterogeneous concept of the state and embraces all actors who are active within the policy process.

9 THE POLITICS OF PROFESSIONAL REGULATION

9.1 Introduction

The previous two chapters have utilised the demand theories and supply theories of professionalisation respectively to analyse the development of professional regulation for CAM practitioners in the UK. Both ignore the interplay between state actors, practitioners and external actors, and fail to identify possible differences among state actors and between professional leaders and grassroots practitioners. This chapter uses 'personal network analysis', which derives from interest group theories, to re-analyse the regulatory process surrounding our five cases of CAM therapies. It is hoped that this perspective will capture the dynamic aspects of the process and provide different insights from those gained using demand and supply theories of professionalisation.

The chapter begins with a short introduction to personal network analysis (see Chapter 5 for more detail) and highlights the main differences from established approaches to policy analysis.

Section 9.3 presents maps of the personal networks showing the key actors, the positions they occupy and the interrelationships between them. The section includes a discussion of the methodological challenges of visualising networks.

Sections 9.4-9.7 analyse four time periods in the policy process. The dynamic interplay between actors in the personal policy networks is examined. Finally, Section 9.8 analyses the particular role of orthodox medical professionals, consumer representatives and academics in the network.

9.2 The CAM policy subsystem

Chapter 5 reviewed the literature on policy subsystems deriving from pluralist accounts of power and interest groups theories. Policy subsystems have been variously called policy communities, issue networks and advocacy coalitions depending on membership, level of integration and resources.

Marsh and Rhodes (1992) presented ideal types of policy subsystems: policy communities and issue networks (see Table 5.4). Policy communities have a limited and stable membership. Members share basic values and interact with each other frequently. They all bring resources and the leaders can deliver members' support. In contrast, issue networks

have many members which fluctuate over time. Although there may be a degree of agreement there is usually conflict. Members have limited resources and the leadership do not have capacity to act with their members support.

According to this typology, the CAM policy subsystem might be classified as an issue network. It is highly fragmented, with a large number of groups who fluctuate in their participation, a disconnection between leadership and membership, and disagreement within and between members. CAM practitioners are generally non-conformist and seem to enjoy arguing among themselves. Although there has been some integration over time, and contact between groups has become more frequent and structured through the seminars and conferences organised by the Foundation for Integrated Health, there are still many groups purporting to represent CAM practitioners.

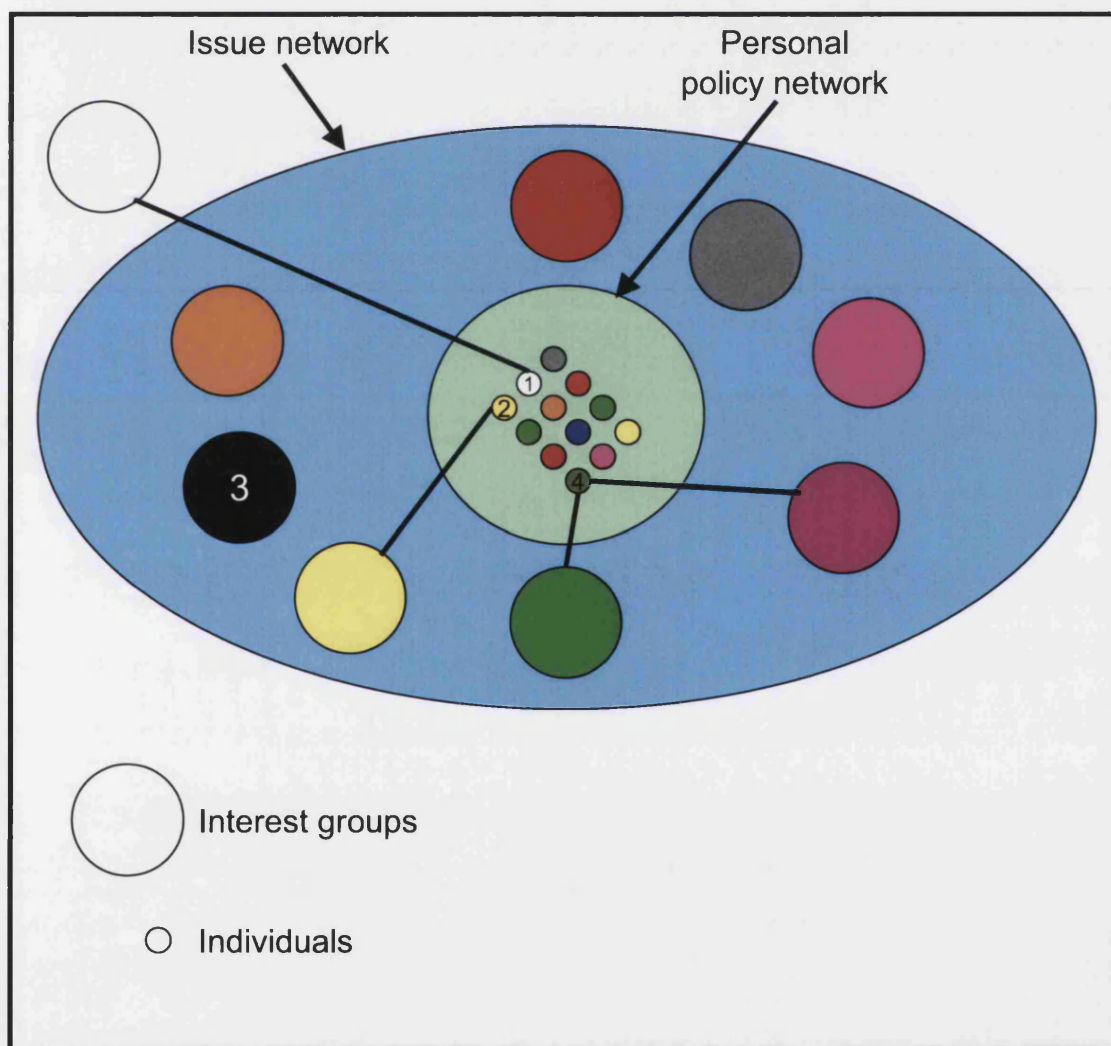
Issue networks are also thought to develop in areas that are of “lesser importance to government, of high political controversy, or in new issue areas where interests have not had the time to establish institutionalised relationships” (Smith, 1993). Again this would seem to fit CAM. CAM policy issues and specifically the regulation of CAM practitioners can be characterised as low politics. There has been some political controversy over the impact of the EU Directive (2004/24/EC) on the availability of herbal medicines and dietary supplements, but not over the regulation of CAM practitioners. CAM policies are less important than other health policy issues. CAM has not featured in any party manifestos and usually falls under the remit of one of the junior Health Ministers. Although this is not a new policy issue - political struggles between orthodox and non-allopathic practitioners have taken place since the late 19th century - rapid growth in the numbers of practitioners and the emergence of new therapies mean there are many new players who have not yet coalesced into stable interest groups.

Analysis of issue networks focuses on organised interests and consequently tends to ignore the role of individuals. Despite the presence of organised groups in the CAM issue network direct involvement in the policy process has been largely limited to a network of individuals including state actors, who use their formal and informal roles to pursue shared objectives. The aim here is to illuminate the role of personal politics in shaping the policy process using personal policy network analysis. The relationship between the wider CAM issue network and the personal policy network, the focus of this study, is depicted in Figure 9.5. While the personal policy network is constituted of individual policy actors, the issue network is made up of interest groups or organisations with an interest in CAM. Although many of the individuals in the personal policy network are affiliated with organisations in the issue network, membership of the two networks does not overlap completely (see

Figure 9.5). For example some individuals within the personal policy network have an affiliation to an organisation outside the issue network (see ① in Figure 9.5). Most individuals within the policy network have at least one affiliation to an organisation within the issue network (see ②) and some have more (see ④). Some organisations in the issue network do not have any individual members active in the policy network (see ③).

In the next section the results of the mapping of the personal policy networks are presented.

Figure 9.5 Relationship between issue network and personal policy network



9.3 Mapping personal policy networks

Personal policy networks are made up of individuals with a variety of affiliations (including state actors) who interact around a common policy issue, in this case the regulation of CAM practitioners. As outlined in Chapter 5, the personal policy network approach adopts a heterogeneous concept of the state. There are many different perspectives that make up the state including those of elected politicians, those of officials and civil servants, and those of peers. Within each of these categories the views might differ between those in opposition and those in power, between back benchers and those on the front bench, between senior officials and low ranking civil servants, and between life peers and hereditary peers.

The first step in the mapping exercise was to produce a list of members of the personal policy network. Members were identified from the documentary data²¹ as well as from among people mentioned by interviewees.

The next step in the mapping exercise involved identifying other information about the members of the personal policy network, such as when they were involved and how actively, their affiliations and interrelationships. These data were then used to produce maps of the personal policy networks at different points in time (see Figure 9.6).

The network maps depict the following information graphically:

- membership at different points in time,
- the roles that each of the individuals has with different organisations - overlapping colour-coded discs are used to represent different affiliations,
- the level of involvement in the process - core members, i.e. those with frequent contact and high levels of engagement, were placed closer to the centre and peripheral members, i.e. those with less frequent involvement, were placed on the edge,
- the relationships between individuals - interconnections are depicted by clustering individuals or placing them in proximity to one another.

Figure 9.6 shows the individuals involved in the CAM personal policy network at four different times – in the early 1990s prior to passing the Osteopaths Act 1993 (A), around 1997 when the Prince of Wales’s Initiative on Integrated Health was formed (B), around

²¹ Names were checked against people who submitted evidence to the House of Lords Sub-Committee, members of committees and working groups, trustees of key organisations, respondents to the Department of Health consultation on the statutory regulation of herbal medicine and acupuncture, published books and papers on CAM regulation and media reports, letters and articles.

2000 when the House of Lords' Sub-Committee on CAM met (C) and around 2003 when the Acupuncture Regulatory Working Group (ARWG) and Herbal Medicine Regulatory Working Group (HMRWG) reported (D). The key to the names of individuals that are included in the personal policy network maps are listed below (for a short biographical profile of these individuals see Appendix 8).

Figure 9.6 Personal policy network maps

Figure A Policy network map circa 1989-1993 - Osteopathy

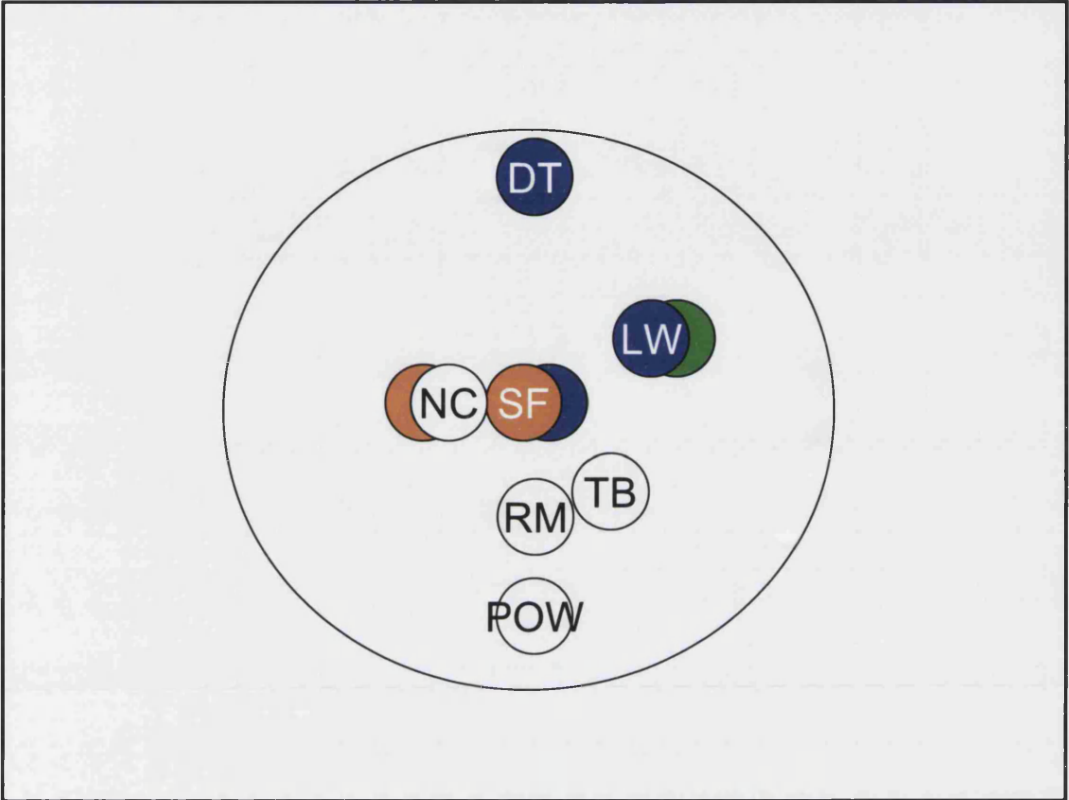


Figure B Policy network map circa 1997 – Prince of Wales

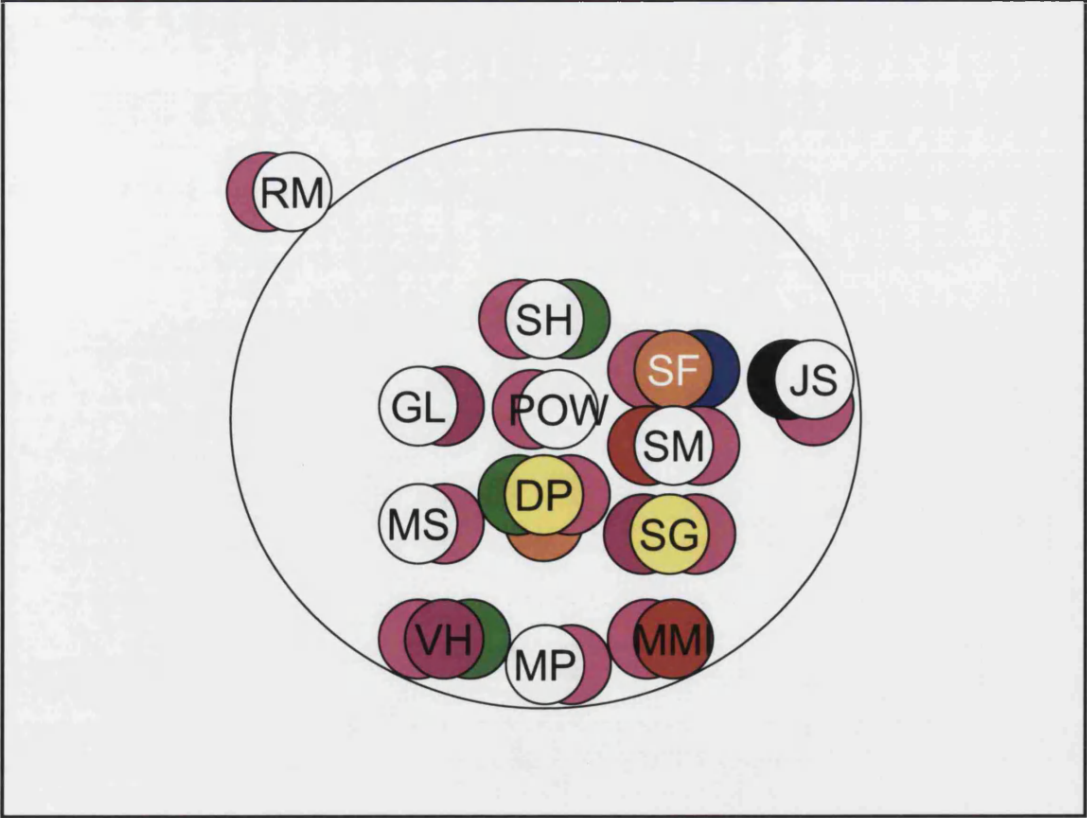


Figure C Policy network map circa 2000 – House of Lords

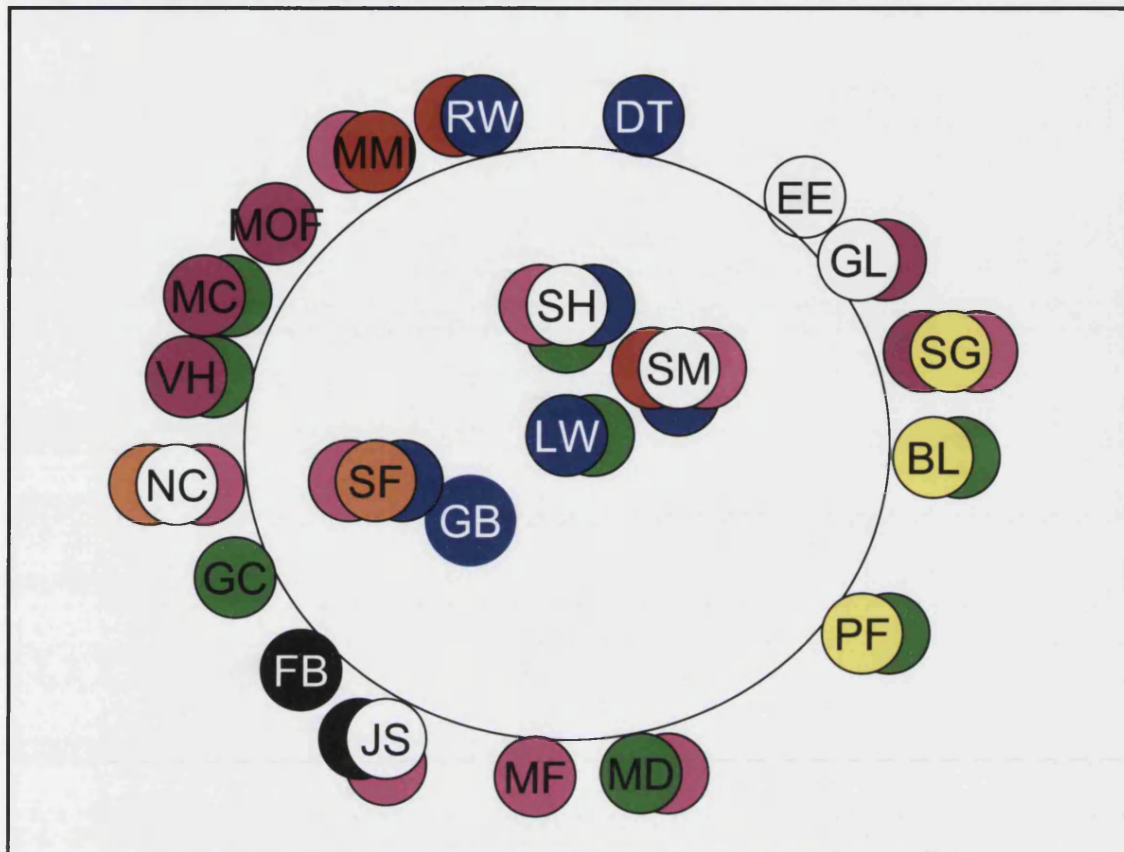
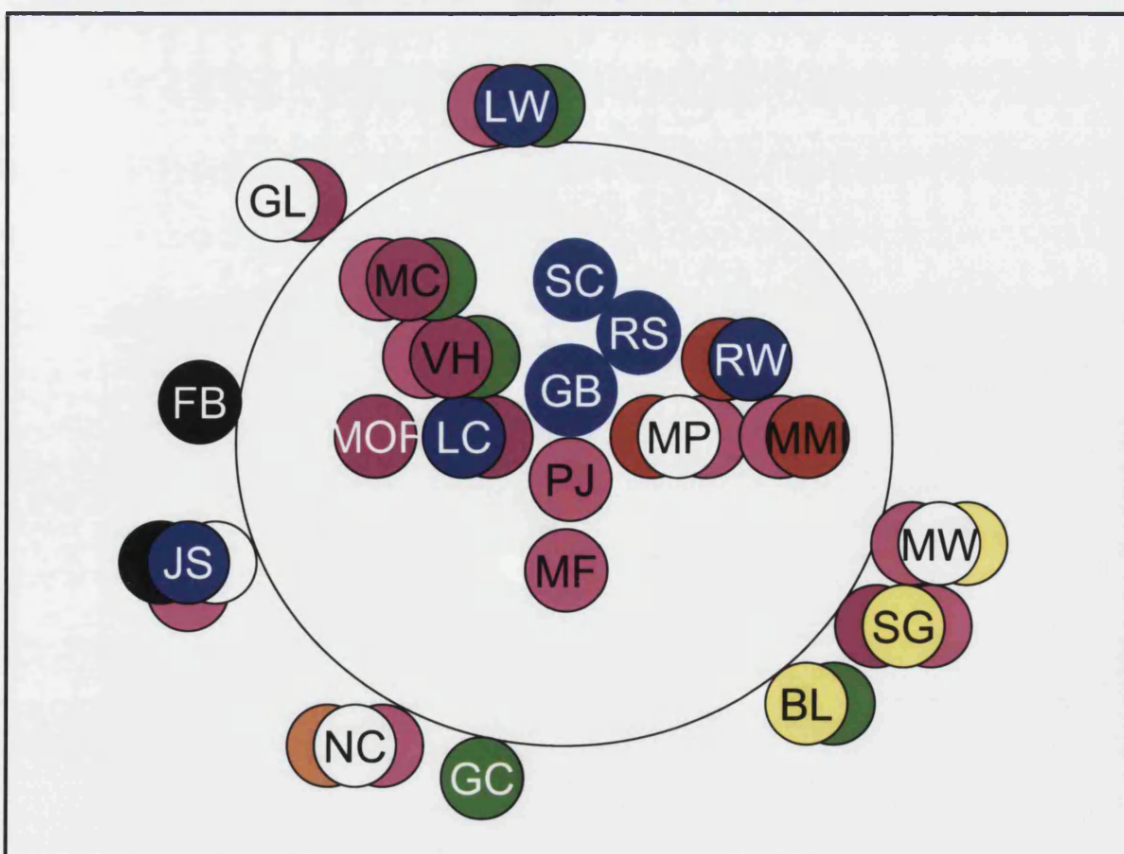












Figure D Policy network map circa 2003 – Regulatory Working Groups



Key:

	Foundation for Integrated Health – staff, trustee		Acupuncture
	Independent – academic, independent chair		Homeopathy
	State actor – civil servant, politician, peer		Herbal medicine
	Consumer organisation		Osteopathy
	Orthodox medicine – practitioner, association or regulator		Chiropractic

BL	Bob Leckridge
DP	David Peters
DT	David Tredinnick
EE	Edzard Ernst
FB	Frances Blunden
GB	Gordon Brown
GC	Graeme Catto
GL	George Lewith
JC	Jonathan Coe
JS	Julie Stone
LW	Lord Walton
LC	Lord Chan
MC	Michael Cummings
MD	Michael Dixon
MF	Michael Fox
MMI	Michael McIntyre
MOF	Michael O'Farrell
MP	Michael Pittilo
MS	Mike Saks
MW	Maggy Wallace
NC	Nigel Clarke
PJ	Pamela Jack
PF	Peter Fisher
POW	HRH Prince of Wales
RM	Robert Maxwell
RS	Rebecca Sidwell
RW	Richard Woodfield
SC	Steve Catling
SF	Simon Fielding
SG	Stephen Gordon
SH	Stephen Holgate
SM	Simon Mills
TB	Thomas Bingham
VH	Val Hopwood

9.3.1 *Overview of the maps*

Membership

It was clear from the outset that the personal policy network under investigation was a small one. In my first interview with the policy lead responsible for CAM policy within the

Department of Health, Gordon Brown (based in the Public Health Directorate) talked about a “sort of inwardness” (Gordon Brown, 2004, para 255). The policy network maps include 34 individuals in total. As can be seen in Figure 9.6 A-D the numbers and diversity of those involved in the network has increased over time.

Most members have a long standing interest and involvement in CAM. For example Simon Fielding got involved as an osteopath who was keen to see the osteopathy profession formally recognised. Even after statutory regulation was achieved he continued to actively participate in the network, supporting and advising other groups seeking to professionalise, and in a formal capacity as a Trustee of the Foundation for Integrated Health. Some individuals maintained an active role despite taking on a new formal role not directly related to CAM. For example Julie Stone’s interest began as a lawyer and academic, in which capacity she wrote about the ethical and legal implications of CAM (Stone and Matthews, 1996). Though she has taken up a formal role at the Council for Healthcare Regulatory Excellence (CHRE) she has continued to work on CAM regulation, writing articles and books and advising the Foundation on their Regulation Programme.

Other individuals were appointed to positions with little prior interest or involvement with CAM but with other relevant experience. For example, Maggy Wallace was appointed as the Chair of the Council for Organisations Registering Homeopaths (CORH). She had previously worked on regulation of nursing and midwifery and as a World Health Organization (WHO) expert on professional regulation. Michael Pittilo was appointed as the Chair of the Acupuncture Regulatory Working Group (ARWG) in 2002 (see Figure 9.6 D). As Dean of St George’s Hospital Medical School he had experience of medical education but not directly of CAM. He first became involved as a member of the Education and Training Working Group for the Prince of Wales’s Initiative on Integrated Medicine (see Figure 9.6 B). Even after the end of his tenure as Chair of the ARWG he has stayed involved, chairing the Working Group for Acupuncture and Herbal Medicine tasked with moving towards implementation of statutory regulation.

There are only a few individuals whose involvement in the policy network was short lived. For example, in April 2003 the specific responsibility for regulation of CAM practitioners was transferred to the Human Resources Directorate (HRD) where Rebecca Sidwell became the responsible official. Reorganisation at the Department of Health during 2004 resulted in Sidwell moving posts at which point Steve Catling, Head of Professional Standards and Pensions, took on responsibility for regulation of CAM practitioners. Sidwell’s involvement was entirely limited to her formal role in the process. Sidwell acted in her official capacity as a civil servant and was involved for less than 18 months, and had no

prior interest in or connections with CAM. In contrast some individuals had little or no connection to CAM in their official capacity and it seems personal interest and contacts primarily account for their engagement in the CAM policy network. For example Sir Thomas Bingham, subsequently Lord Chief Justice of England and Wales 1996-2000, who chaired the King's Fund Working Parties on Osteopathy and Chiropractic, was a personal friend of Robert Maxwell (Chief Executive of the King's Fund at the time).

Affiliations

The policy network is made up of individuals whose affiliations span a wide range of stakeholders including the civil service and government agencies, the House of Commons and the House of Lords, universities, charitable foundations, consumer organisations, professional regulators, practitioner organisations and professional associations. Most individuals occupy senior positions as senior executives, trustees, professors, committee chairs, board members and directors.

Many individuals served or continued to serve in a number of capacities, thus strengthening the interconnectedness of the CAM policy network. For example, Julie Stone is Deputy Director at the CHRE and Visiting Professor in Health Care Ethics at the University of Lincoln. She is a member of the Foundation For Integrated Health's Regulatory Action Group and was employed by them as a consultant to prepare a report on the future of voluntary regulation for CAM practitioners. She is also involved with consumer interest organisations. She previously served on the board of the Prevention of Professional Abuse Network (POPAN) and is currently a member of the Clinical Disputes Forum Committee.

Identifying an individual's affiliations to different organisations is an important aspect of mapping the personal policy network. Few people have a single interest which they represent, even where they hold formal office, but rather are influenced by their various allegiances.

Relations

Within the policy network there are both formal and informal connections between individuals. Clustering and proximity are used to portray this aspect of the policy network.

At a formal level people are clustered because they work within the same organisation. For example Rebecca Sidwell, Gordon Brown and Steve Catling are all civil servants in the Department of Health and are clustered together in Figure 9.6 D. Richard Woodfield who works for the Medicines and Healthcare products Regulatory Agency (MHRA) is a civil servant and therefore connected with other staff in the Department, but as the main policy

lead on herbal medicine he was closely involved with the HMRWG chaired by Michael Pittilo and of which Michael McIntyre, Chair of EHPA, was a key member.

Other connections are informal and more hidden. For example Dr Peter Fisher, who is Vice President of the Faculty of Homeopathy, Clinical Director of the Royal London Homeopathic Hospital and editor of the British Homeopathic Journal, is also homeopath to the queen and acquainted with Prince Charles. Michael Dixon, Chair of the NHS Alliance, a trustee of the Foundation for Integrated Health and Senior Associate at the King's Fund, is a GP who practises complementary therapies and has personal connections to HRH the Prince of Wales.

9.3.2 *Methodological challenges*

There is increasing interest in the application of policy subsystem analysis to health care policies and health care reforms (see for example Oliver and Mossialos, 2005). The advocacy coalition framework has recently been applied to an analysis of pharmaceutical policy reforms in Denmark (Larsen, Vrangbaek et al., 2006). There is, however, little in the literature on methods for representing policy communities, advocacy coalitions or issue networks graphically. Most studies simply present tables that categorise actors but these do not show the interrelationships between actors. Stakeholder analysis depicts the position of groups along a two dimensional axis according to their influence or interest in the policy issue under analysis (see for example Varvasovszky and McKee, 1998). Weible and Sabatier (2005) present a series of network maps showing clusters of actors based on analysis of their membership in ally, coordination, and information networks (Weible and Sabatier, 2005).

The analysis here is at the level of the individual, and therefore seeks to depict not only clusters of actors and their relationships but also their associations with different stakeholders. The use of colour coded disks to represent an individual's primary association and additional associations allows the depiction of relations and affiliations. This technique for representing policy networks would not be possible in most academic publications.

A limitation of the approach utilised here is that the positioning of individuals is largely a result of personal judgement. Whereas inclusion of individuals and their position in the core or on the periphery are justified, their position *vis a vis* other actors is based on what are judged to be their primary connections. For practical reasons not all interconnections can be depicted in the maps.

The process of developing the maps was useful in clarifying my own understanding of the policy process and the role of individuals within it. It provided new insights into the

relative importance of different players and the significance of particular organisations to which they were affiliated. The maps also provide a useful way of depicting the personal policy networks and summarising large amounts of information (in the same way that a graph or chart conveys numeric data). The following sections analyse the personal policy networks in more detail to see what further insights can be gained into the development of statutory regulation for different CAM therapies. I examine who was involved, the role played by different members and their relationships with other members of the personal policy network. The analysis is not strictly chronological but takes a snapshot of the policy process at a particular time and uses it to identify the role of and relationships between individuals in the policy network at that time. Past and future events may be discussed where these are useful to explain an individual's involvement in the policy process.

9.4 Peers and politicians assist the osteopaths

In the late 1980s and early 1990s the activity in the field of CAM regulation was focused on the osteopaths. At the centre of the policy network that was mobilised on this issue was Simon Fielding, a practising osteopath (see Figure 9.6 A). Fielding was the first Chairman of the General Osteopathic Council (GOsC) and has been the Department of Health's special adviser on complementary medicine since 1993.

The analysis in chapter 7 suggested that in the case of the osteopaths the process which culminated in the Osteopaths Act 1993 was strongly driven from within the profession. Personal network analysis suggests that the energy of one individual was crucial to the success of the professional drive for regulation. Nigel Clarke, who later became Chair of the GOsC, claimed "Simon Fielding...was the man really substantially responsible for CAM regulation in this country being statutory at all" (Clarke, 2005, para 5). Fielding was frequently mentioned during the debate of the Osteopathy Bill in the House of Commons. He was credited with the progress and success of the Bill and his presence in the public gallery was acknowledged (against the rules of parliamentary conduct!). Malcolm Moss MP paid tribute to Fielding "for his personal commitment and dedication in seeking to acquire statutory regulations for his profession" (Hansard, 7 May 1993). Tom Sackville MP for the government said:

I also add my congratulations on the sterling work performed by Simon Fielding in the profession's quest for statutory regulation. Mr. Fielding, himself an osteopath, has worked ceaselessly for that cause virtually all his professional life. He was a key member of the King's Fund Working Party and also played a vital role in persuading my hon. Friend the Member for Cambridgeshire, North-East to sponsor his current Bill. It is not only fitting but justly deserved that he has recently been appointed chairman of the General Council and Register of Osteopaths (Hansard, 15 January 1993).

Fielding was not in an official leadership position in a professional association at this time but his personal connections were instrumental in achieving the outcome. His relationship with Clarke, who became a fellow protagonist in the formation of the GOsC, was particularly significant. Clarke recounts their encounter in the mid-1980s; "I met him ten years before. We were introduced by a lawyer, we were mutual clients. He wanted to know how to go about getting statutory regulation for osteopaths" (Clarke, 2005, para 5). Clarke had experience of parliamentary and political affairs through work at the House of Commons, for the Home Secretary, William Whitelaw, and at the Conservative Research Department. He was working for a public policy consultancy when he met Fielding. He recounted how:

In those days I was doing a lot of political work so I helped him sort out his campaign, work out how he needed to do it, what work he needed to do actually to get anyone to support the principle. Things like the King's Fund exercise in 1989 were a result of that. It was the need to get a greater buy in to the idea and to also establish what needed to be done in order to provide a structure that was meaningful (Clarke, 2005, paras 5-6).

He continued to support Fielding in the development of the Bill and joined the GOsC at its inception as a lay member (1996). He was subsequently appointed as Treasurer in 1997 and Chair in 2001, in which capacity he is a member of the CHRE.

Fielding had another important ally – HRH the Prince of Wales. In 1988 Prince Charles hosted a lunch at Kensington Palace which was attended by Health Ministers, presidents of the royal medical colleges and the President of the General Medical Council (GMC) as well as Fielding (Hansard, 15 January 1993). This event was a turning point in winning support from the orthodox medical profession. Tom Sackville MP acknowledged the importance of the lunch; "At the end of their discussion, the presidents said that they believed that the way was clear to proceed with proposals to secure the statutory regulation of the osteopathic profession" (Hansard, 15 January 1993).

Fielding, encouraged by this, sought support for drafting a bill and putting it to parliament. He approached Robert Maxwell, then Chief Executive of the King's Fund, of which HRH the Prince of Wales is the President. Maxwell recalls that "an extremely nice osteopath" came to see him "more or less out of the blue" to ask if the King's Fund were prepared to help "move things on for the osteopaths" (Maxwell, 2005, paras 17-19). They discussed the possibility of setting up a high level working party that would do the drafting work for a Bill. Maxwell took the idea to the King's Fund Management Committee for approval. They agreed "relatively quickly" to support the working party financially, and to find the people to sit on it.

Maxwell approached Tom Bingham, a personal friend whom he had known "since Oxford days" who later became Lord Chief Justice (1996-2000) and is now Lord Bingham of Cornhill. He agreed to chair the Working Party on Osteopathy which was set up in autumn of 1989. Bingham proved a terrific choice: committed, determined to go for simple solutions, and totally lacking in pomposity or self-importance (Maxwell, 2005). The King's Fund were thanked directly in the discussion of the Bill, which was one of the longest to be introduced as a Private Members' Bill. The bulk of the Bill was written by the Working Party, although the government's solicitors later revised and re-drafted it.

Towards the conclusion of the process the support of key individuals within the House of Commons and House of Lords was vital to the osteopath's success. Another King's Fund 'friend', Lord Walton of Detchant, agreed to introduce the Bill in the House of Lords. Lord Walton served as a member of the GMC for 18 years, the last seven as President (Walton, 2005), and as President of the British Medical Association (BMA) until 1982 (succeeded by HRH the Prince of Wales). The Bill went before the House of Commons with support from David Tredinnick MP and William Cash MP, both members of the All Party Parliamentary Group on alternative and complementary medicine. The Bill received widespread support but its passage through parliament was interrupted by the general election in 1992.

The Bill won a Private Members' ballot and was reintroduced in the next parliament by Malcolm Moss MP. On this occasion there was explicit government support for the Osteopaths Bill given by the Parliamentary Under-Secretary of State for Health, Tom Sackville MP, who it turned out had "a personal, family interest". He revealed that:

I have just discovered - to my shame, only a few minutes ago - that my late father was the president of the General Council and Register of Osteopaths - [Laughter.] He was a dark horse. I was aware that he was active in another place in promoting the interests of the profession, but the fact that he reached such heights has only just come to my attention (Hansard, 15 January 1993).

Government support for the Bill meant it had an easy passage. The Osteopaths Act became law in May 1993.

Many of the same individuals were involved in the policy network at the time the chiropractors were seeking statutory regulation (not shown). The chiropractors were “upset” that the osteopaths were moving ahead faster. The King’s Fund agreed to convene a second Working Party once the work with the osteopaths was finished (Maxwell, 2005, para 31). Tom Bingham agreed to chair the Working Party on Chiropractic. The plan was to bring forward a second Private Members’ Bill to regulate chiropractors.

Ian Hutchinson, who was Chair of the British Chiropractic Association (BCA), played a leadership role among the chiropractic profession. David Lidington MP, opening debate on the Chiropractor’s Bill, acknowledged that “Members of the chiropractic profession and the steering group, under the chairmanship of Ian Hutchinson, have been enthusiastic, supportive and full of information” (Hansard, 18 February 1994). Hutchinson wrote about his role in the process (Hutchinson, 1994), though his name was not mentioned by any interviewee nor is there evidence that he remained involved after this time. Chiropractors benefited from the momentum generated by the osteopaths. Hutchinson benefited from the network established by Fielding. In introducing the Bill to the House David Lidington MP thanked Malcolm Moss MP, who had introduced the Osteopaths Bill, “for blazing a trail which I am now able to follow” (Hansard, 18 February 1994).

The policy network map (Figure 1.A) depicts the central position of Simon Fielding in the network in the early 1990s. The analysis suggests he played a crucial role in the osteopathy profession successfully gaining statutory regulation. Fielding might be described as a ‘policy entrepreneur’.

To sum up, the personal policy network was largely constituted of people with personal connections, rather than formal affiliations. The main players included a public policy expert (Nigel Clarke), a high profile advocate (HRH the Prince of Wales), the Chief Executive of an independent health foundation (Robert Maxwell at the King’s Fund), a leading lawyer (Tom Bingham), activist politicians (Malcolm Moss MP, David Lidington MP, and David Tredinnick MP), and a well respected leader of the orthodox medical

profession (Lord Walton). The association of a high profile and well respected lawyer and a former President of the BMA and GMC, together with sponsorship by the King's Fund, gave legitimacy to the osteopaths' bid for statutory regulation.

Perhaps crucial was the personal interest of HRH the Prince of Wales (Brown, 2004) who himself confessed that he "took a particularly close interest" in the statutory regulation of osteopaths and chiropractors (Prince of Wales, 1997). The next section explores in greater detail the role of HRH the Prince of Wales in the policy process.

9.5 HRH the Prince of Wales

Figure 1.B depicts the policy network in 1997 when HRH the Prince of Wales launched his personal Initiative on Integrated Health. The royal family have historically been patrons of homeopathic medicine (see Chapter 4), and holistic medicine has long been a personal interest of HRH the Prince of Wales. According to his official website he has "nearly 25 years of interest and involvement in the field of holistic medicine" (Prince of Wales, 2005a, para 9). Michael Dixon of the NHS Alliance believes Prince Charles is the "biggest mover behind integrated medicine" (Dixon, 2005a).

On 14th December 1982, in one of Prince Charles' first major speeches as President of the BMA and on the occasion of the 150th anniversary dinner, he expressed his hope of greater integration between complementary and orthodox medicine (Prince of Wales, 1982). He criticised orthodox medicine for losing "sight of the patient as a whole human being, and...reducing health to mechanical functioning" (Prince of Wales, 1982, para 11). Integrated medicine was the "main thrust" during his time as President of the BMA. He wanted to bring about a "general cultural change" and a "change in professional views" by making a "direct appeal to doctors" (Dixon, 2005a, para 20). It was under his Presidency that two contrasting reports were produced by the BMA on alternative medicine (British Medical Association, 1986; British Medical Association, 1993) (see below for further discussion of the role of the orthodox medical profession).

In 1986 HRH the Prince of Wales became President of the King's Fund, by virtue of rules set down by an Act of Parliament in 1907 under which the King Edward's Hospital Fund for London was incorporated (Maxwell, 2005). As President he has had some influence over its sponsorship and support for the professionalisation of CAM practitioners. Robert Maxwell commented that "it was clear from the beginning that complementary medicine was one of the fields in which he had a strong interest" (Maxwell, 2005).

HRH the Prince of Wales convened and chaired a seminar in February 1996 “to review the current situation and to discuss what practical steps should be taken to further communication and cooperation between all concerned in the provision of healthcare services” (Prince of Wales, 1997). It was agreed during this seminar to establish a series of Working Groups on four themes: Research and Development, Education and Training, Regulation, and Delivery Mechanisms.

The Prince of Wales’s Initiative on Integrated Health involved over 80 people over an 18 month period. The map only depicts those identified members of the personal policy network who were involved in the Steering Committee or one of its Working Groups. The Steering Committee also formally consulted with “a wide range of individuals and organisations in both the orthodox and complementary healthcare fields, as well as providers and consumers” including “the royal colleges, leading researchers, professional organisations like the BMA, and some of the leading medical schools and bodies representing complementary medical practitioners” (Prince of Wales, 1997, para 20). The outcome of the deliberations were published in 1997 (Foundation for Integrated Medicine, 1997). Prince Charles used the occasion of the inaugural King’s Fund President’s lecture to launch the discussion document (Prince of Wales, 1997, para 6). The process was facilitated and supported by the Foundation for Integrated Medicine established in 1996.

The Foundation, which later became the Prince of Wales’s Foundation for Integrated Health, is a “charity formed at the personal initiative of His Royal Highness, The Prince of Wales” (Prince of Wales, 2005b, para 5). Prince Charles’ involvement is financial – he made a ‘substantial contribution’ to the £2 million endowment with which it was established (Prince of Wales, 2005a, para 12); professional - he is the President of the Foundation and personally vetted the appointment of the first Chief Executive, Michael Fox (Fox, 2004, para 57); as well as personal - Prince Charles often refers to the Foundation as ‘my Foundation’.

The Foundation has been extremely influential in the development of regulation for CAM practitioners (see below). A glance at the policy network presented in Figures 1.C and 1.D shows that the majority of people have a connection to the Foundation. The list of past and present trustees is impressive (see Appendix 9). In a sense the Foundation is the glue which holds the policy network together. It explicitly acknowledges this role:

The Foundation's great strength lies in its ability to foster networks across conventional and complementary boundaries by working alongside professional bodies in both fields, national and local governments and the NHS. This web of contacts helps draw together people from diverse backgrounds to build bridges, share experiences, exchange information and instigate new collaborative projects (Foundation for Integrated Health, 2003).

The influence of the Foundation is in large part due to its President; “the impact of the Foundation has been considerable in this area and that’s been helped with the involvement of the Prince of Wales who has strongly spoken of the importance of better regulation for CAM practitioners” (Fox, 2004, para 282). There continues to be close affiliation with HRH the Prince of Wales. Sir Michael Peat, who has worked in the Royal Household since 1993 (most recently as Private Secretary to HRH the Prince of Wales) was appointed Chairman in 2005 following the departure of Dame Lesley Rees. Thus through the Foundation, HRH the Prince of Wales has set up an effective mechanism to push his agenda of integrated health and holistic medicine.

Since its launch in 1996, the Foundation has been the main vehicle through which HRH the Prince of Wales has participated in the policy network and influenced policy on CAM regulation. He has also used other formal roles at the BMA and the King’s Fund, the media and informal occasions to push this agenda.

In 1999 the King’s Fund agreed a £1 million grant for the Foundation’s Regulation Programme. While there is no suggestion that there was a direct link between HRH the Prince of Wales’s role at the Fund and the grant to the Foundation the two organisations share a President. Michael Fox, Chief Executive of the Foundation admitted, “it’s very unusual for the King’s Fund to give a million pound grant, it’s not chicken feed” (Fox, 2004, para 151). He went on to say that, “I don’t think they would have given a million pounds just because the Prince of Wales thought it was a good idea” (Fox, 2004, para 151). A similar admission of indirect influence was mentioned by Graham Hart, a former Chairman of the King’s Fund Board, “Of course the Prince of Wales is President of the KF [King’s Fund] and was pleased if we could help FIM [the Foundation]. But there were good policy reasons for the grants” (Hart, 2004). The Foundation used the funds to organise seminars on education and training, professional accreditation and ethical professional practice, and to establish a number of professional fora chaired by individuals who were independent of the professions, each tasked with developing a single voluntary system of regulation. The King’s Fund launched its new funding priorities for the *Partners for Health in London* programme in 2004 which includes integrated health as one of four streams.

There are some 18 speeches and newspaper articles by HRH the Prince of Wales on the theme of integrated health or complementary and alternative medicine on his official website. In 2006 he gave the key note address at WHO's 59th World Health Assembly (Prince of Wales, 2006). He also commissioned economist Christopher Smallwood to investigate the contribution which complementary therapies could make to the delivery of healthcare in the UK (Smallwood, 2005). This caused considerably controversy and debate. Edzard Ernst, Professor in Complementary Medicine at the University of Exeter, criticised the report for being "highly selective in its use of evidence". He went on to say "it looks like the conclusions have been written before everything else. It is based on such poor science it's just hair-raising." Finally in a direct criticism of Prince Charles, Ernst accused him of overstepping his constitutional role (Henderson and Pierce, 2005). Evan Harris MP, the Liberal Democrat science spokesman who got involved in the ensuing debate, felt that Prince Charles should stay out of public policy discussions. He remarked that:

If Prince Charles is going to seek to influence healthcare or science policy especially without going through the normal peer review process he must allow himself to be challenged in debate or interview, something that he has never done. If the Palace believes that it is not appropriate for him to lower himself into public debate, then he should stay out of public policy (Henderson and Pierce, 2005).

In order to establish more accurately the extent of involvement of HRH the Prince of Wales in the policy process a Freedom of Information request was made to the Department of Health requesting correspondence on this issue from Clarence House (see Appendix 10 for request and full response). In the Department's reply they clarified that the constitutional position of the Heir to throne is the same as that of the Sovereign. They wrote that the Sovereign has

the right and duty to counsel, encourage and warn her government and is entitled to have opinions on government policy and to express those opinions to her ministers. It is essential that these communications are, and remain, confidential, to maintain the political neutrality of the Sovereign in public affairs (Department of Health, 2005a).

On these grounds the Freedom of Information request was refused.

The main motivation behind Prince Charles' interest in the regulation of CAM practitioners is his hope that regulation will facilitate greater integration. In 2003 he acknowledged "if the NHS is being encouraged to provide a more integrated approach, then it does, quite rightly, require reassurance that complementary medicine is being offered by competent practitioners" (Prince of Wales, 2003, para 17). HRH the Prince of Wales was at the centre

of the policy network in 1997 when he established the Foundation for Integrated Health. Although Prince Charles is “frustrated” and is getting “impatient” because things are moving a “bit slow”, his Foundation has had a huge influence on policy (Dixon, 2005a). HRH the Prince of Wales used his other formal positions at the BMA and the King’s Fund to further this agenda, and used his public profile to keep the issue on the public policy agenda.

9.6 Those who sit in another place

Figure 1.B depicts the policy network at the time of the House of Lords’ Sub-Committee on Complementary and Alternative Medicine during the parliamentary session 1999-2000. Lord Walton of Detchant, who had served on the Science and Technology Committee for ten years, was appointed as Chair of the Sub-Committee. He appears at the centre of the policy network map (see Figure 1.C). A full list of members can be found in Appendix 11.

Lord Walton had been a key supporter when the osteopaths attempted to gain statutory regulation (see Figure 1.A). He presented the Osteopaths Bill before the House of Lords following the report of the King’s Fund Working Party on Osteopathy. He also supported the passage of the final Osteopaths Bill when it came back to the Lords from the Commons. According to Nigel Clarke, who together with Simon Fielding was largely responsible for the momentum behind the osteopaths (see above), “Lord Walton ... was within his own lights the guiding force for this” (Clarke, 2005).

The membership of the Sub-Committee was determined by the Committee of Selection which contains “people from all the political parties and a number of cross benchers” (Walton, 2005). The government, Chief Whip and Ministers are usually involved behind the scenes. Names are then put to the House. Among the members of the Sub-Committee were Earl Baldwin and Lord Colwyn, who were Joint Chairman and President of the Parliamentary Group on Alternative and Complementary Medicine respectively, and Lord Rea, Lord Soulsby, and Lord Winston, who were all registered medical practitioners.

By Lord Walton’s own admission opinions within the Sub-Committee diverged but despite this the report, published on 21st November 2000, was a unanimous report. He recounted how:

We almost got to the stage, almost of having a division. Because you can never produce a minority report for a Select Committee in the House of Lords or the Commons. That is not allowed. If there is a major difference in opinion then you have to have a division in the Committee and have a vote...I mean the Committee consisted of hawks and doves and there was one hawk in particular who almost took it to a division but in the end agreed that it would be a unanimous report (Walton, 2005, para 143).

The ‘hawks’ presumably refers to the supporters of biomedicine who were opposed to any recommendations which might give CAM greater legitimacy, and the ‘doves’ those who were overtly in favour of CAM.

The only other people depicted within the core of the policy network are Stephen Holgate and Simon Mills, who were appointed as special advisers to the Sub-Committee, Gordon Brown, who was the lead civil servant working on the issue and who coordinated the government response, and Simon Fielding, who was now an adviser to the Department of Health. What is noticeable is that each of the advisers was also connected to the Foundation and involved in Working Groups of the Prince of Wales’s Initiative on Integrated Health (see Figure 1.B). For instance, Holgate and Mills served as Chairman of the Research & Development Working Group and Co-Chairman of the Regulation Steering Group respectively.

In such a small policy network getting independent advice was a challenge. As a Department official conceded:

There were certain connections. I mean let’s face it we have a difficulty in the world of CAM as with other specialities, where do we go for expert advice? You have to go to the world of CAM for your expert advice, and inevitably some of those experts were already well known to the Foundation and working quite closely with it and some of those experts were lending a hand to the Inquiry, they were engaged by the Inquiry and lending a hand. (Brown, 2004, para 255).

However as the Lords’ Inquiry demonstrated, there are many doctors, academics and scientists who can ask very pertinent questions even when they lack expertise in CAM (Brown, 2006).

Consequently, the work of the House of Lords’ Sub-Committee was influenced by the Foundation. In reviewing their first five years of achievements the Foundation noted how the House of Lords’ report “closely mirrored the Foundation’s objectives, set out in its 1997 discussion document” (Foundation for Integrated Health, 2003). For example, the five key themes around which the Foundation organised its work programme were very

similar to the topics set out in the House of Lords' call for evidence issued on 28th July 1999 (House of Lords' Select Committee on Science and Technology, 2000b). The recommendations of the House of Lords' Sub-Committee also reflected the Foundation's recommendations on regulation (House of Lords' Select Committee on Science and Technology, 2000a). Although these interconnections existed and there was "sympathy" for CAM among some of the Sub-Committee's members, they were sufficiently independent and robust in their questioning that "they gave them [the Foundation] a good run for their money" (Brown, 2004, para 255).

As many as 156 organisations and 45 individuals submitted written evidence to the Sub-Committee. As described in the methodology (see Chapter 6) not all of these were included in the analysis. Those individuals identified as members of the policy network who submitted written evidence or gave oral evidence are displayed on the periphery of the network (Figure 1.C). Some individuals were involved in more than one submission. Michael McIntyre gave evidence as Chair of the European Herbal Practitioners Association (EHPA) and as a Trustee of the Foundation for Integrated Medicine. Professor Edzard Ernst submitted written evidence as an individual and prepared the Memorandum for the Royal College of General Practitioners.

The selection of who was called to give oral evidence was important in the balance of arguments that were heard and of course different weight was given to the written evidence of different organisations and individuals. For example Michael Fox, Chief Executive of the Foundation for Integrated Health "had a good reception", in part because of the unique lead the Foundation had taken in developing united self-regulation (Brown, 2004, para 255). The Institute for Complementary Medicine (ICM), one of the few bodies representing and registering a range of therapies, accused the Sub-Committee of having given weight to the views of "a so called 'umbrella' body representing a limited range of CM disciplines", probably meaning the Foundation, while totally ignoring their own evidence (Baird, 2001).

The ICM made other accusations that the process was biased and that the civil service had "advised Ministers of the findings of the Sub-Committee before the official publication of the Report" (Baird, 2001). The speed with which the government published its response (in March 2001) suggests that the government knew what the major recommendations of the Committee were going to be in advance of publication. The speed of the response was interpreted by some people as an indication of the urgency within the Department to take action. The Chief Executive of the British Acupuncture Council commented:

What was interesting...was the speed at which the government responded...my perception is that 8 out of 10 of these committees that are set up, the reports come and they're stuffed in the drawer. But this was three or four months later, we got a response (O'Farrell, 2004).

The government response was also “immensely supportive. There was hardly anything with which they disagreed” (Walton, 2005, para 163). Lord Walton of Detchant, who had previously chaired a number of Select Committees, admitted this was “quite unusual” (Walton, 2005, paras 165-7).

Several of those interviewed highlighted the importance of the House of Lords' Sub-Committee in the regulatory process. It was credited with raising political interest in CAM regulation. Officials at the Department of Health believed that the House of Lords' Report was the main driving force behind the move towards professional self-regulation for CAM practitioners. One official said:

without that [the Lords' Report] I can't really see that there would have been the drive within the Department because it wasn't a big enough issue. And I think it was the House of Lords' Report which generated the ministerial interest. And without that we wouldn't really be where we are today (Sidwell, 2005, para 15).

Another official expressed similar views that, “the priority like most things in the Department was seasonal in the sense that most of it grew out of the Lords' Select Committee Inquiry on CAM which we had to respond to” (Brown, 2004, para 35).

The recommendations of the House of Lords' Sub-Committee were shaped by a group of supportive Lords (the ‘doves’), a sympathetic Chair (Lord Walton of Detchant), and advisers who had close associations to the Foundation. The public profile of the Lords' Inquiry gave a forum for stakeholders to present their views, as well as putting the issue firmly on the agenda of Department of Health officials and Ministers. The next section examines their role in the next stage of the policy process.

9.7 Mandarins and their Ministers

Following the government's response to the House of Lords' Report (March 2001) the policy process shifted its focus to the development of proposals for the statutory regulation of acupuncture and herbal medicine. The responsibility fell to civil servants and their Ministers to determine a process for this. The decision was taken by Hazel Blears MP, then the Minister responsible for CAM, to establish two regulatory working groups - the Acupuncture Regulatory Working Group (ARWG) and the Herbal Medicine Regulatory Working Group (HMRWG) – jointly with the Foundation for Integrated Health. The

Foundation had already established working groups with independent lay chairs for several CAM therapies, including herbal medicine, as part of the Regulation Programme funded by the King's Fund. In January 2002, when the Working Groups began their work, Gordon Brown was the civil servant in charge. He is placed at the centre of the policy network together with Pamela Jack, Manager of the Regulation Programme at the Foundation (see Figure 1.D).

Brown had been in post for a number of years and was well-liked by CAM practitioners within the policy network. Michael McIntyre, President of the EHPA referred to him as "our Gordon Brown...wonderful man" (McIntyre, 2004). His knowledge of the issues was also recognised by the medical acupuncturists (Cummings, 2005, para 152). Brown knew the CAM world and developed close working relationships with members of the network. Michael Fox, Chief Executive of the Foundation for Integrated Health, commented that Brown "knew his way round the territory" and his contribution to the process should not be underestimated (Fox, 2004, para 111). According to Pamela Jack, "Gordon was very knowledgeable and supportive of our work so his retirement has been a loss to us. There has been a lack of continuity in our contact with the civil service since his retirement" (Jack, 2004, para 210). The continuity of contact with the civil service came to an end with Brown's retirement in August 2004.

Other changes within the Department during this period added to the lack of continuity. Yvette Cooper MP, who served as Parliamentary Under Secretary of State for Public Health from October 1999, was replaced by Hazel Blears MP in May 2002. In June 2003, she was moved to the Home Office during a Cabinet reshuffle. John Hutton MP, Minister of State for Health 1998-2005, was upset to discover at this time that regulation of CAM practitioners was not under his direct responsibility. Otherwise all policies concerned with professional regulation were part of his Ministerial portfolio. He demanded that he should be in charge of subsequent policy decisions on the regulation of CAM practitioners (McIntyre, 2004). The transfer of ministerial responsibility was accompanied by a shift in internal departmental responsibility. As part of the overall reorganisation that emphasised functional roles and challenged traditional demarcations, responsibility for professional regulation was brought together within the Human Resources Directorate (HRD). Rebecca Sidwell was appointed within HRD to take responsibility for the regulation of CAM practitioners.

From April 2003, Sidwell and Brown were jointly responsible for the Working Groups until they reported in September that year. Subsequently, Sidwell was responsible for developing the government's proposals, organising the public consultation and

summarising the responses of the consultation. As explained previously, at the end of August 2004, as a result of further reorganisation and rationalisation, Sidwell was transferred to another post and was not replaced. The responsibility for regulation of CAM practitioners was assumed by Head of Professional Standards, Steve Catling. The process then stalled in anticipation of the outcome of two reviews into the future of professional regulation, which were announced in 2005 and reported in summer 2006 (Chief Medical Officer of England, 2006; Department of Health, 2006c). A consultation is underway on the proposals of these reports, which are discussed further in the concluding chapter (Department of Health, 2006a).

The herbalists were fortunate to have a civil servant within the Medicine Control Agency (later the Medicines and Healthcare products Regulatory Agency). Richard Woodfield, Group Manager Herbal Policy, has been at the MHRA with responsibility for herbal medicines since about 1997. As he himself noted “Remarkably for a civil servant I’ve dealt with herbals all that time though the other parts of my job have constantly changed” (Woodfield, 2004, para 24). This allowed the herbalists to build up strong relationships with officials.

The close relationship between officials and leaders of CAM practitioner groups within the personal policy network was seen by one official as peculiar to CAM. She commented that:

Previously the Department had been resourced to take a more step by step approach with the professions. It had done so with chiropractic and osteopathy and I suppose it was a natural continuation of that (Sidwell, 2005, para 107).

She believed the process would have been different if it had been led by the Health Regulatory Bodies Branch within HRD from the beginning. In general, support for and interest in CAM has increased within the Department of Health since the House of Lords’ Inquiry, according to Lord Walton, “they [the Department] are much more sympathetically disposed towards the whole area.” (Walton, 2005, para 115).

9.7.1 Independent Chairs

Beyond the civil servants and staff at the Foundation the other core members of the policy network were the chairs and members of the two Regulatory Working Groups. The search for chairpersons began in September 2001 with appointments taking effect from January 2002 (Pittilo, 2004). Professor Michael Pittilo, Vice Chancellor of the University of Hertfordshire and formerly Dean at St George’s Hospital Medical School, London, was appointed Chair of the HMRWG. Lord Chan of Oxton, a paediatrician, former Director of

the Ethnic Health Unit in the Department of Health, and Professor of Ethnic Health at Liverpool University until his untimely death in February 2006, served as Chair of the ARWG.

Michael Pittilo was approached on Michael McIntyre's recommendation - they had met through the Education and Training Working Group, part of the Prince of Wales's Initiative on Integrated Health (See Figure 1.B) and were both trustees of the Foundation for Integrated Health. Pittilo seems to have quickly established good relations with the Department of Health and became widely respected within the policy network as an independent and reasonable voice. He had the time to develop consensus around the proposals by making presentations at conferences and speaking to the different groups involved. Even after the HMRWG had reported he remained involved, talking to the medical acupuncturists and representing their concerns to the Department (Pittilo, 2004, para 335) and continues to chair the working group of acupuncturists, herbalists and traditional Chinese medical practitioners.

Lord Chan was an enthusiastic and committed Chair. He allowed lots of discussion and debate within the Group although differences between group members were not fully resolved. He was willing to support the Order through the House and to stand up as an advocate in favour of regulation (Sidwell, 2005, para 152). As the only peer of Chinese origin his selection as Chair was expected to facilitate discussion with the traditional Chinese medicine (TCM) lobby but "instead of being sympathetic to their plea for special treatment he took a very strong line against them" though he brought them into the discussions at an appropriate stage (Brown, 2004, para 673). In fact Lord Chan was not willing to include 'TCM-ers' in the Group because they were too fragmented (with at least six different factions), they wanted their own Working Group and they did not accept that regulation was necessary (Chan, 2005, paras 32-36). Some TCM practitioners are members of the British Acupuncture Council (BAcC) and therefore were represented in the discussions from the outset.

9.7.2 *Members*

Membership of the Regulatory Working Groups was largely drawn from the leadership of the established professional associations that had voluntary registers of practitioners. In herbal medicine, except for the Association of Traditional Chinese Medicine (ATCM) and the British Ayurvedic Medical Council/British Association of Accredited Ayurvedic Practitioners (BAMC/BAAAP), all of the organisations represented on the HMRWG were

already members of the EHPA and were used to cooperating under that umbrella. The ATCM subsequently joined the EHPA.

Michael McIntyre, as President of the EHPA, was the main professional stakeholder on the Group who had existing links to the key policymakers through his involvement with the Foundation (see Figure 1.B). He and Amrit Ahluwalia, the Secretary of the HMRWG, also acted as brokers outside the HMRWG “to encourage positive dialogue between organisations and make sure everyone is understanding the others point of view” (Sidwell, 2005, para 145).

In acupuncture, there were two practitioner representatives from each of the four main professional organisations: the British Acupuncture Council (Jasmine Uddin and John Wheeler), the British Medical Acupuncture Society (Anthony Campbell and Mike Cummings), the Acupuncture Association of Chartered Physiotherapists (Joan Davies and Val Hopwood) and the British Academy of Western Acupuncture (Peter Dowds and Paul Mayer). Only Mike Cummings and Val Hopwood were identified as active members of the personal policy network. Although the practitioner representatives from the BAAC were the official members of the Working Group it was the Chief Executive Michael O’Farrell who brokered agreement on regulation of acupuncture and therefore was included as a core member of the personal policy network (see Figure 1.D). O’Farrell joined the BAAC from the private sector where he had worked for Kodak. He was seen as independent, “balanced”, a strong leader and was able to establish good relations with officials at the Department (Sidwell, 2005, para 100). He was influential beyond his role at the BAAC. He did “an awful lot of work in trying to get the different sides of the profession to talk to each other and to talk to the TCM practitioners and the TCM organisations” who had largely been excluded from the ARWG discussions (Sidwell, 2005, para 80).

9.7.3 *Reports and recommendations*

The civil servants apparently went into the process without a blueprint for regulation. To those involved there did not appear to be a clear plan and so members of the policy network were actively involved in shaping policy together with civil servants. Rather than policy being made behind closed doors and then imposed on the profession, the leading representative of the herbalists felt it was made in partnership (McIntyre, 2004). Others, however, felt excluded. Representatives of Ayurvedic medicine were extremely unhappy with the process, threatening legal action at one point and dissenting from the final report. BAMC/BAAAP arrived at one meeting of the Working Group with a lawyer who “issued an injunction” against all those present (McIntyre, 2004, para 45). The representatives from

BAMC/BAAAP maintained that there should be separate regulation for Ayurvedic Medicine (Herbal Medicine Regulatory Working Group, 2003, para 49). Traditional Chinese medicine practitioners, for whom acupuncture and herbal medicine are both integral parts of their practice, felt excluded from the discussions in the ARWG and that the recommendations were not workable for them.

The ARWG and HMRWG made different recommendations about how to structure statutory regulatory bodies (discussed in further detail in the next chapter). These reflected both the views of the chairs (see below) and leading members of the profession involved with the Groups. The proposals for a single General Acupuncture Council reflected a compromise within the ARWG with the medical acupuncturists.

The Working Group reports and the consultation went before John Hutton MP for approval. The proposals which were put forward for consultation by the Department largely reflected the recommendations of the HMRWG i.e. to create a single CAM Council. The proposals were met with discontent from the acupuncturists who felt that their proposals had been ignored. They even took the non-alphabetical order of the therapies in the title of the document as a slight!

Ministers were pleased with the progress made towards regulation and, although the issue was not a particularly high priority, they were pleased with the publication of the consultation and the positive response it received (Sidwell, 2005). The consultation mainly focused on questions of how to organise a new CAM Council, the decision having already been taken to introduce regulation. Responses from individuals shown on the periphery of the policy network map are analysed in the next chapter which focuses on ideas about how to regulate CAM practitioners.

9.7.4 *Summary*

The osteopaths and chiropractors needed political allies in the House of Commons and the House of Lords (see Figure 1.A) in order to get legislation passed. Because the regulation of acupuncture and herbal medicine was government-led, departmental and ministerial support has been more significant. Hence the centrality of civil servants to the policy network at this stage (see Figure 1.D).

Michael McIntyre was the key policy entrepreneur for the herbalists. He established strong relations with long-serving civil servants and used the opportunities presented by external policy developments in Europe to ensure that herbalists were at the top of the list. The development of proposals was facilitated by an independent ally (Michael Pittilo), whose connections with the Foundation, other authoritative individuals within the policy network

(e.g. Simon Fielding) and with civil servants meant herbalists' interests remained central to the government's proposals.

Within acupuncture the focus was on reaching consensus between lay acupuncturists and medical acupuncturists, a process facilitated by Lord Chan as Chair of the ARWG and outside the formal proceedings by Michael O'Farrell. There may be a number of reasons why their recommendations were not given as much weight by the Department. Firstly, the exclusion of traditional Chinese medical practitioners from the ARWG meant their report was narrow in focus. Secondly, the MHRA saw that significant improvements in the effectiveness of medicines regulation (where unlicensed herbal medicines are made up by or for herbal practitioners) were dependent on the introduction of statutory regulation for the herbal medicine profession (Woodfield, 2004). Finally, the failure of the medical acupuncturists to explain to officials their particular needs and constraints, assuming that the case was adequately stated in the report. These factors may have been compounded by the absence of a policy entrepreneur from within the profession and the fragmentation of the profession.

Much of the progress that acupuncture and herbal medicine have made in preparing for statutory regulation can be put down to the active support of civil servants and the mediating role of the Working Group Chairs. The policy network from 2003 onwards has taken on a more traditional pattern with representatives of organised interests interacting and negotiating with officials in the Department, although individuals such as Michael Pittilo continue to play an active mediating role in the process.

9.8 Other actors

The focus in the previous section has been primarily on practitioner representatives, politicians and civil servants directly involved in the policy process. Other actors such as orthodox medical practitioners, representatives of consumer organisations and academics were also involved in the policy process, but often less directly. This section considers their roles in the personal policy network.

9.8.1 Orthodox medical practitioners

There are a number of individuals in the policy network who are orthodox medical practitioners (bright green in the maps). Many of these individuals are sympathetic to CAM or practise integrated medicine themselves. For example, Michael Dixon is a practising GP who uses complementary therapies in his practice, as well as serving as the Chair of the NHS Alliance, Senior Associate at the King's Fund, and Trustee of the Foundation for

Integrated Health. Prince Charles is a great supporter of homeopathy and has personal links with leading medical homeopaths Peter Fisher, Vice President of the Faculty of Homeopathy and Clinical Director of the Royal London Homeopathic Hospital, and David Peters, who was a member of the Steering Committee and Chairman of the Delivery Mechanisms Working Group for the Prince of Wales's Initiative on Integrated Health.

Sir Graeme Catto, President of the GMC, is involved by dint of his formal position and knowledge of professional regulation, while Lord Walton of Detchant is included because of the formal positions he has held and personal interest. Although Catto's direct involvement with CAM practitioner groups has been limited to giving advice to the Regulatory Working Groups, it is likely that having someone who is open to CAM as President of the GMC is indirectly helpful to the CAM policy network. As we have seen, Lord Walton, who in the past had been President of both the GMC and the BMA, became an important ally from within the medical profession for the osteopaths and chiropractors. Later, as Chair of the House of Lords' Sub-Committee on CAM, he was able to ensure balance between those members who were pro-CAM and those more traditional medics who were perhaps more sceptical. These practitioners, active in the personal policy network, are not typical of the wider orthodox medical profession.

Interviewees and documents analysed in this study referred to the changing views of the medical profession. There was a sense that earlier antagonisms were waning. Michael McIntyre, Chair of the EHPA, recounted how in the early 1980s trainee GPs had been "hostile" towards herbal medicine. He felt there had been a "huge sea change" and doctors today take a more "positive standpoint", are interested in where they can train, and in how to identify practitioners to which they can refer (McIntyre, 2004). In evidence to the House of Lords the Royal College of Physicians and the GMC both recognised that doctors need to be familiar with CAM therapies in order to discuss them with their patients (House of Lords Select Committee on Science and Technology, 2000a, paras 6.71-6.72). Graeme Catto, Chairman of the GMC Education Committee at the time of the House of Lords' Inquiry, went further and suggested that some doctors "will wish to become involved, through the special study modules, in undertaking some treatments themselves or experiencing, along with patients, what is happening" (General Medical Council, 2000b, para 1037).

There has also been a shift in attitudes to CAM among the leadership of orthodox medicine. In 1988, the leaders of the medical profession were encouraged not to block the Osteopaths Bill. Following the lunch hosted by Prince Charles attended by Ministers and leaders of the profession (mentioned previously), Tony Newton MP, then a junior Minister

in the Department of Health and Social Security (1982-88), urged the doctors to stand aside. According to the Chair of the General Osteopathic Council:

[Newton] quietly behind the scenes suggested that the doctors ought to accept that this was going on and they might not like it and they might not agree with it, but the public needed to be protected, and therefore standards must be set and there needed to be ways of shoving out the snake oils and the charlatans (Clarke, 2005).

This shift is also evident in the different positions taken in the BMA reports on CAM. Under the presidency of HRH the Prince of Wales the Board of Science and Education of the BMA published a report on Alternative Therapy in 1986 which was scathing of CAM (British Medical Association, 1986). Statements such as “it is apparent that many of those who adhere steadfastly to belief in a given ‘alternative’ therapy have halted in their intellectual progress” provoked a furious reaction from CAM practitioners and no doubt from their President (British Medical Association, 1986, p 63). The report claimed that alternative therapists had “much in common with the folk healers of primitive societies” and emphasised the dangers and risks of therapies. In particular it raised concern at the risks that arise from:

delaying or denying access to effective medical care by persistence with alternative therapies which are without a beneficial effect on the developing disease process at a time when orthodox medical treatment is urgently needed (British Medical Association, 1986, p 74).

The second report published in 1993 had a much more conciliatory tone reflected in its title - *Complementary Medicine: new approaches to good practice* (British Medical Association, 1993). By the time of the House of Lords’ Inquiry, the BMA recommended that:

a single regulating body should be established for each therapy...[with] a single register of members, open to public scrutiny...a defined protocol for communicating with medical practitioners and other therapists...clearly understood areas of competence...enforceable ethical code...well publicised and accessible complaints procedures (British Medical Association, 2000, p 46).

The Royal Colleges have taken a different position, often emphasising that given the lack of evidence for the efficacy of CAM it should not be regulated. For example, the Royal College of General Practitioners continued to “question whether there is need for statutory regulation at all as, particularly with herbal medicine, this implies a scientific basis which may not be justified” (Baker, 2004).

Orthodox medical practitioners have used arguments about indirect risk to defend their monopoly over diagnosis. For example, medical homeopaths, although supportive of regulation for non-medical homeopaths, were keen to maintain their position. They were worried that if lay practitioners were regulated it might reduce demand for homeopaths with medical training. They emphasised the indirect risks associated with non-medical practice, and justified their own position by emphasising the importance of a medical diagnosis and medical supervision for the safety of patients. Medical acupuncturists made similar claims that “any patient with a new symptom should gain a western diagnosis before seeking therapy” (British Medical Acupuncture Society, 2000, para 1007). Arguments about indirect risk are not new and have long been viewed as protectionism of professional monopoly (see HMSO, 1910). As a result many therapies have positioned themselves as complementary to mainstream medicine, e.g. aromatherapy, and make limited claims.

9.8.2 Consumer representatives

The main consumer organisations that comment on health policy in the UK are Which? (formerly known as the Consumers’ Association), the National Consumers’ Council and the Patients’ Association.²² Of the three organisations Which? has been the most active on CAM regulation. Although the National Consumers’ Council published a report on professional regulation in 1999 (National Consumer Council, 1999), they have not specifically undertaken work relating to CAM practitioners. The Patients’ Association gave oral evidence to the House of Lords’ Sub-Committee, but were not mentioned by members of the policy network.

The Consumers’ Association (CA) states that it campaigns for “improved protection for users of complementary and alternative therapies, particularly where there is a risk of physical or emotional harm arising from sub-standard care” (Consumers Association, 2004, para 9). The CA recognises that where there are direct risks statutory regulation may be the only regulatory option available. It states that:

For some therapies this [voluntary regulation] may be sufficient where the risks and extent of any potential harm are minimal...However, for some CAM therapies, there is no real alternative to statutory regulation if public protection and safeguarding the public interest are to be ensured (Consumers Association, 2004, para 15).

The CA published Health Which? magazine with a regular feature on CAM until recently and as Which? continues to publish special consumer reports on CAM (Which?, 2006). In

²² There are many other patient groups related to specific diseases but these were not active in the debates about CAM.

response to a consumer survey, which revealed a lack information on which to base choice of practitioner, the CA commissioned a survey of CAM practitioner organisations in June 1997 (Bloomfield, 1997). Their position has been that statutory regulation of all CAM therapies is not desirable or practical, that even with protection of title rogue practitioners can continue to practise, and that the government needs instead to produce guidance for consumers and fill the “information gap” (Consumers Association, 2000; Department of Health, 2000b; Consumers Association, 2004).

Frances Blunden, Principal Policy Adviser at Which?, has a long-standing personal interest in professional regulation stemming from her previous job at POPAN (Blunden, 2004), a registered charity concerned with the abuse of patients by professionals in the health and social care sector (POPAN, 2000, p167). She wrote the evidence that POPAN submitted to the House of Lords’ Sub-Committee (Blunden, 2004). Blunden felt that practitioners desire for regulation was largely self interested “because regulation gives you status...you start to have a controlled closed shop effectively so it does give you status, opportunity to bid up, all sorts of things like that” (Blunden, 2004, para 95).

Jonathan Coe was appointed Chief Executive of POPAN in 2002. He has quickly become an active member of the policy network (see Figure 1.D) and has good connections with the Foundation, where he represents the consumer perspective at seminars and meetings. POPAN has been lobbying for the inclusion of psychotherapy in policy discussions about CAM practitioner regulation, and for recognition of emotional harm (POPAN, 2000; Coe, 2004; Coe, 2005). Psychologists and psychotherapists were excluded from the terms of reference of the House of Lords’ Inquiry because they “made it perfectly clear that they regard themselves as being part of conventional medicine, not complementary medicine” (National Institute for Clinical Excellence, 2000, para 1849). Hypnotherapy and psychotherapy have the largest number of complaints made against practitioners by patients.²³ POPAN emphasise the need for consumer information, effective complaints systems with specialist advocacy services, and audit and evaluation of professional services. They have an ally in Julie Stone who was a trustee of POPAN.

There are a number of other small, CAM-specific lobby groups which were active in the wider issue network. For example Healthwatch, one of whose patrons is Lord Walton of Detchant, who chaired the House of Lords’ Inquiry into CAM, supports and encourages scientific testing of conventional, complementary and alternative medicine and therapies. It is highly sceptical of CAM therapies that are promoted without any evidence of efficacy.

²³ The lack of regulation of psychotherapy and counselling has long been a concern to consumer organisations such as POPAN. The government have recently committed some funding to try and develop a consensus on proposals for unified regulation of the professions (Coe, 2005).

Although a charity with aims related to consumer protection and public understanding of science, most of its founding members appear to be from the orthodox scientific community.

Public mobilisation has focused on the regulation of herbal products. It was the agreement on the EU Pharmaceuticals Directive (2001/83/EC) which the UK signed up to in October 1994 (and which came into force in January 1995) that precipitated a more active public campaign. The herbalists launched a very successful high profile media campaign with support from the producers of over-the-counter herbal products and some high profile donors to ensure that herbal medicines were excluded from the provisions of the Pharmaceuticals Directive. Richard Woodfield at the Medicines and Healthcare products Regulatory Agency (MHRA) recalls that in the mid-1990s:

there was a good deal of controversy about whether or not, or if so, how manufactured herbal medicines should be included in [the EU Pharmaceuticals Directive] and there was a major controversy and that actually ended with the status quo largely prevailing which meant the existing UK regime for unlicensed herbal remedies (Woodfield, 2004).

The MCA apparently had to draft in extra people to reply to the letters that they received on this topic, and MEPs were deluged with letters (McIntyre, 2004).

The public were again mobilised when the EU Directive on Traditional Medicinal Products (2004/24/EC) was being implemented. Although it created a much more favourable legal situation than might have resulted from the earlier Directive, commercial interests were still concerned that the new rules would limit the availability of herbal medicines, vitamins and supplements. The constitution and activities of consumer groups reflect these concerns. For example Consumers for Health Choice galvanised consumer pressure in order to fight EU legislation. The campaign got funding and support from UK manufacturers and the National Association of Health Stores, and through leafleting, celebrity endorsement and media coverage was successful in generating large numbers of letters to MPs and MEPs. The Health Freedom Movement is an umbrella organisation formed to coordinate opposition to EU legislation. According to its own materials, its membership includes complementary medical associations, therapist and practitioner groups, patient rights consumer groups, retailers, distributors, manufacturers, the media, publishing companies and existing organisations opposed to the EU Directives (Health Freedom Movement, , para 4). Like Consumers for Health Choice its specific purpose was to “raise consumer awareness about the regulatory threats to complementary and alternative medicine, and to rally the public’s support to fight their implementation” (Health Freedom Movement).

Other than Frances Blunden and Jonathan Coe, few representatives of consumer organisations have been active in the policy network. The common positions of POPAN and Which? may reflect the fact that Blunden has had formal roles in both organisations during the period of study.

9.8.3 *Academics*

The knowledge base to support CAM therapies is highly contested. Consequently, academics have become embroiled in debates about its safety and harms, its efficacy and causal effect. Yet the position of academics has largely been on the periphery of the policy network (see Figures 1.A-D).

A number of academics have established an interest in CAM research. Edzard Ernst was appointed as Professor in Complementary Medicine at the University of Exeter in 1993. He has written extensively about the need to establish the efficacy of CAM treatments using rigorous scientific research methods. Although he published on this subject throughout the period of study, his relationship with other members of the policy network has been controversial with frequent spats in the media. His opinion that there is little or no evidence for most complementary therapies has won him few friends among CAM practitioners. He has also been critical of the Foundation's work, particularly of the Department of Health funded guide for patients (Pinder, 2005). Most recently he leaked details of the Smallwood Report on the cost effectiveness of CAM treatments commissioned by the Prince of Wales. Consequently, he is depicted on the periphery of the personal policy network and never penetrates to the core. His closer allies are to be found among the orthodox medical profession and consumer organisations such as Healthwatch who cite his research.

George Lewith established the Complementary Medicine Research Unit at Southampton University in 1995. The Centre has established a reputation for conducting high quality clinical research on efficacy of CAM therapies and the role of the placebo effect, and has attracted funding from established sources including the Department of Health and the NHS (Lewith, 2005). Lewith's main influence has been on policies related to research and development. He was involved in the Prince of Wales's Initiative on Integrated Health, gave evidence to the House of Lords, and hosted a visit to Southampton by members of the Sub-Committee. Val Hopwood (President of the Acupuncture Association of Chartered Physiotherapists until 2005/6) works with him as a Research Fellow, and Stephen Holgate (who was a specialist adviser to the House of Lords' Sub-Committee) is

MRC Professor of Immunopharmacology at the University of Southampton and another of Professor Lewith's collaborators.

Mike Saks is Pro-Vice Chancellor (Research and Academic Affairs) at the University of Lincoln. His academic research as a sociologist focuses on professionalisation and CAM (Saks, 1986; Saks, 1991; Saks, 1994). He was a member of the Prince of Wales's Initiative on Integrated Health (see Figure 1.A) but has not remained involved with the Foundation. He did not give evidence to the House of Lords. He has few active links within the core of the policy network, although he has recently been appointed onto the Department of Health Complementary and Alternative Medicine Research Policy Committee.

Simon Mills, Director of the Centre for Complementary Health Studies, University of Exeter is also a member of the Council of the Foundation for Integrated Health. Together with Sarah Budd he co-authored a series of reports for the Department of Health which were extremely influential in highlighting the inadequacies of voluntary regulation, but which also set out options for how regulation should develop (Budd and Mills, 2000; Mills and Budd, 2000). He was later appointed a special adviser to the House of Lords' Committee (see Figure 1.C).

Finally, Julie Stone (in her role as Visiting Professor in Health Care Ethics at the University of Lincoln) uses her academic affiliation to continue to write about CAM regulation in a personal capacity (Heller, Lee-Treweek et al., 2005; Stone, 2005a). Her direct involvement in the policy network is mostly through her other associations with the Foundation or CAM practitioners (see Figure 1.B and 1.C). Stone combines her professional legal perspective with an understanding and knowledge of CAM practitioners and a consumer orientation from her involvement with POPAN. She has persistently argued that statutory regulation is not appropriate for most CAM therapies, but that "the form of regulation needs to reflect the differences between individual therapies and their respective harms, since different therapies require different levels of regulation" (Stone, 2000, p286). She has challenged others' "somewhat uncritical assumption that statutory regulation of health professionals provides the best or only acceptable form of patient protection" (Stone, 2000, p286).

She is critical of the pursuit of statutory self-regulation by CAM practitioners and writes:

For most therapies, the rush towards statutory regulation as opposed to professionalisation is misguided. Rather than binding themselves within an inappropriate statutory straitjacket, most therapies should continue working towards accreditation and the development of national standards of training and competence. Consumers will be best protected by a dynamic, ethics led approach to voluntary self-regulation in which standards of practice and visible and effective disciplinary procedures are given higher prominence than the pursuit of professional status (Stone, 1996).

In evidence to the House of Lords she argued that there is no justification for mandatory licensing of all CAM practitioners because the therapies do not pose an inherent risk of serious harm, and that any harm is equally capable of occurring in a statutory context (Stone, 2000). She has advocated instead for a well-publicised voluntary system.

Academics have had a limited influence on the policy process with only one or two within the core of the personal policy network. They have played different roles depending on their research agendas and their position on different policies. Ernst can be seen as the thorn in the side for many practitioner organisations and the pro-CAM lobby. In contrast, although Lewith also advocates for scientific research he is seen as an ally of those in the policy network. Among those working on regulation specifically, Saks's sociological perspective has had a weaker influence compared to Stone's legal perspective. The application of Stone's more prescriptive and normative research may have been easier for policy-makers to understand than descriptive and theoretical research.

9.9 Discussion

As shown in Chapters 7 and 8, theories of professionalisation have some value in explaining why the regulation of CAM practitioners has taken the form it has in the UK. Yet, their exclusive focus, on either CAM practitioner groups or the state, means the role of individual actors in the policy process is overlooked. CAM regulation is not the stuff of traditional high politics where powerful external interests are at play or where significant cross-governmental interests are at stake. It is a small somewhat incestuous community made up of a tight network of individuals who hold key positions in different organisations with little organised or vocal opposition. CAM has therefore been a particularly fitting policy context in which to study the policy process using personal network analysis. As discussed in the conclusions, further applications of this approach to other areas of policy with similar characteristics would help to determine its wider relevance.

This chapter has shown how analysis of personal policy networks can illuminate the dynamic relationships between individuals, including people from outside practitioner

organisations and government circles. The analysis enables a deeper exploration of how the policy process operates in practice, and exposes the diversity of roles played by individuals. It challenges both theory and empirical analysis that assumes professional organisations and the state are unified entities. The state does not operate in a vacuum, and policies are not the product of a rational policy process (though some have described it in such terms (Simon, 1947)). The process of policy-making is a messier affair. As Greer noted in his recent analysis of devolution and health care policy:

Civil servants, academics, the press, and other politicians can all affect the outcome by shaping the politicians' impression of the costs and benefits of a policy and thereby influence whether the politician will adopt the proposal in response to political opportunities and problems (Greer, 2004, p 13).

To his list I would add practitioners and professionals, consumer organisations and royalty. The personal network analysis has tried to examine these interactions in the policy process.

The analysis identified key individuals who acted as policy entrepreneurs or policy brokers. These individuals usually had a range of formal roles in different organisations, but also informally pushed the policy agenda forward or mediated between different interests and individuals. Policy analysis focused at the level of organisations might have overlooked these people and the crucial role they played in the policy process. The study threw up one very surprising finding. It revealed a significant role for HRH the Prince of Wales in the policy process. Officially the Sovereign (and by default the Heir to the Sovereign) may advise their Ministers privately but their neutrality must be preserved. Controversially it seems that HRH the Prince of Wales has played an active and public role in shaping policy. His influence on other areas of public policy in which he has a personal interest such as architecture, organic farming and the environment would be worthy of further analysis.

Representatives of consumer organisations and academics were also active within the personal policy network but played a less significant role. The issue of CAM practitioner regulation has not been a priority issue for consumers, and this is reflected in the activities of consumer organisations present in the wider issue network. The rhetoric around regulation is dominated by concerns to protect the public, and yet ironically consumers (and their representatives) have had little influence or voice in the policy network.

Despite enthusiasm for evidence-based health policy (Murray and Lopez, 1996; Murray and Frenk, 2001) most academic research has a limited influence on policy (Cookson, 2005). The analysis here found that few academics penetrated the core of the policy network or influenced the development of regulatory policy. Some academics through their other

formal or informal affiliations interacted with other members of the policy network. However, the academic whose views were opposed to those held by the majority of the members of the policy network was side-lined.

In this chapter the use of personal policy network analysis has deepened our understanding of the policy process as experienced by the actors within it. However, the actions and interactions between individuals examined here cannot be said to explain why statutory regulation occurred in some cases. The concluding chapter discusses the value of the personal policy network approach and considers its application to other areas of policy. In the next chapter we turn to the second part of the research question, which asks why the model of professional self-regulation was adopted for CAM practitioners.

10 IDEAS ABOUT PROFESSIONAL REGULATION

10.1 Introduction

The previous three chapters have focused on the question of why particular CAM therapies in the UK have been statutorily regulated. We now turn to the question of why regulation has taken the form that it has. There are many approaches to regulation (as was shown in Chapter 3) and yet the preferred policy in the UK has been to adapt the medical model of professional self-regulation. Like other healthcare professionals before them, some CAM practitioners have achieved legal rights to control entry to the profession and been granted protection of title by the state. This chapter seeks to explain why the medical model has dominated regulatory policy. Following theories about the role of ideas in shaping the regulatory process developed in Chapter 5, this chapter examines the ideas about models of regulation promoted by CAM practitioner groups, the state and other key individuals in the policy network.

Section 10.2 begins by presenting the medical model of professional self-regulation. This ‘ideal type’ has been modified and applied to other health care occupations over the past century (see Chapter 4 for more on the history of the professions). It is also currently undergoing reform. Section 10.3 examines ideas about protection of title and presents discussions about how this would apply to CAM practitioners. While the General Medical Council (GMC) regulates a single profession, other statutory regulators including the Health Professions Council (HPC) and the Nursing and Midwifery Council (NMC) regulate several professions. Section 10.4 analyses the debates about whether CAM therapies should be regulated as individual therapies or under a joint or federal arrangement. Finally, many CAM practitioners practise more than one therapy and there are large numbers of statutory health care professionals who also practise CAM. Section 10.5 examines the options that have been discussed to accommodate this.

Section 10.6 examines ideas about the appropriate governance structures of regulators. The discussion is largely focused on the representation of professionals and the lay public. There appears to be a growing consensus among professionals and policy-makers on this issue. Any profession setting up a new register must determine what the entry requirements are. Section 10.7 analyses the debates about the level and type of standards that a registering body should require of new registrants and existing practitioners wishing to register.

Section 10.8 takes a closer examination of the views of orthodox medical practitioners, representatives of consumer organisations, and academics in order to try to identify alternative ideas to the medical model. The final section draws on the theoretical literature on policy ideas and paradigms and discusses why there was so little exploration of alternative models of regulation within the policy network.

10.2 The medical model of professional regulation

The history of professional regulation in health care can be traced back to the Medical Act 1858 when doctors gained statutory recognition (see Chapter 4 for historical background). In some senses the GMC, which the Act established, is the *Urmodell*²⁴ of professional self-regulation. Freidson viewed the medical profession as the “prototype upon which occupations seeking a privileged status today are modelling their aspirations” (Freidson, 1970, pxviii).

The original functions of the GMC set out in the Medical Act 1858 were:

- the oversight of medical education and the examinations leading to qualification;
- the registration of qualified practitioners and the publication of the Medical Register;
- the removal from the Register of practitioners convicted of felony (Section 29);
- the prosecution of unqualified practitioners who had presented themselves as licensed;²⁵
- the publication of a British pharmacopoeia.

The functions of the GMC as set out in the Medical Act 1983 and which apply today are:

- Setting the standards of good medical practice which society and the profession expect of doctors throughout their working lives;
- Setting the content of basic medical education and assuring its quality, promoting high standards and coordinating all stages of medical education;
- Administering systems for the registration and licensing of doctors to control their entry to, and continuation in, medical practice;

²⁴ In German “Ur-” is used as a prefix denoting original, first or primary for example “Urmensch” meaning prehistoric man. “Modell” is German for prototype or pattern. The use of “Urmodell” captures the idea of an ideal type or original model of medical regulation to be captured in a single compound noun.

²⁵ Today those who hold themselves out as registered practitioners, i.e. use, or imply, any of the prohibited titles or descriptions, are prosecuted through the courts.

- Dealing firmly and fairly with doctors whose fitness to practise is questioned (Chief Medical Officer of England, 2006).

The statutory governing body (the Council) is accountable to the Privy Council.²⁶ It has a professional majority (made up of a mixture of elected and appointed professional members) and lay representatives.

The GMC first introduced reforms to undergraduate medical education in 1993 (since updated see General Medical Council, 2003), and explicit standards of practice in 1995 (recently revised see General Medical Council, 2006). Performance was added to conduct and ill health as part of fitness practice in 1995, and the fitness to practise procedures were streamlined in November 2004. Changes to the composition of the Council increased the proportion of lay members. Revalidation, however, remained an intention rather than a reality, despite earlier plans to introduce it by 1st January 2005 (Catto, 2006).

The government created the Council for Healthcare Regulatory Excellence (CHRE) to promote best practice in professional self-regulation, and under Section 29 of the NHS Reform and Health Care Professions Act 2002 gave it powers to refer cases to Court where the decisions of fitness to practise committees were judged unduly lenient (Department of Health, 2000e; Department of Health, 2001b). The CHRE's role was not universally welcomed by regulators, even though the presidents of the statutory councils each automatically have a seat on the CHRE.

Despite these changes to its constitution (e.g. increasing lay membership), its Committee structure and its fitness to practise procedures, the fundamental functions and elements of the GMC have not changed. Other regulators that were subsequently established have copied the *Urmodell* in most respects, though there is great variation in the size, scope, income, governance and operations of these bodies (see Allsop, Jones et al., 2004 for detailed information on each of the health care professional regulators in the UK).

In 2005 the government launched two internal reviews into professional regulation: the first headed up by the Chief Medical Officer to look at the future of medical regulation, and the second addressing the regulation of non-medical health care professionals (Chief Medical Officer of England, 2006; Department of Health, 2006c). This was not the first time that medical regulation had come under scrutiny. In 1975 the Merrison Committee was set up to undertake a review of medical regulation. The Committee actually reaffirmed

²⁶ Draft rules require the approval of the Privy Council. In practice that means that each House of Parliament must pass a resolution in favour of the relevant statutory instrument (Allsop, Jones et al., 2004).

the principles of self-regulation. Professional self-regulation remained largely unchallenged until as recently as 1997 (Department of Health, 1997).

Adverse publicity surrounding a number of high profile failures by the GMC to identify and discipline errant doctors brought renewed pressure to enhance public accountability of regulators. Cases such as the deaths of babies undergoing surgery at Bristol Royal Infirmary were first reported in the media in 1995.²⁷ In 1998 the government challenged the professions to demonstrate that professional self-regulation deserved the public's confidence (Department of Health, 1998). The reports of several public inquiries raised serious questions about the ability of doctors to police themselves. In particular, the report of the public inquiry into the deaths in Bristol, chaired by Sir Ian Kennedy and published in 2001, was a turning point in the discussion of professional self-regulation (Bristol Royal Infirmary Inquiry, 2001).

Public inquiries were also held into the cases of individual doctors (Ayling, Neale, Kerr and Haslam and Shipman). In January 2001 Dame Janet Smith was appointed to chair a public inquiry into the murders committed by Dr Harold Shipman between 1972-1998. The Inquiry's Terms of Reference required:

[an examination of] the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision ... and to recommend what steps, if any, should be taken to protect patients in the future
(Department of Health, 2004b).

Most of the interviews I conducted preceded the publication of her 5th Report in December 2004 that dealt with these issues. Interviewees expected her to make some radical suggestions about the future of professional regulation and recognised the significant impact the case had on professional regulation. For example, the Manager of the Regulation Programme at the Foundation for Integrated Health stated that the Shipman case "has changed the public perception of regulation and of health professionals, of the risks involved and so on" (Jack, 2004, para 398). Dame Janet recommended that the adjudication function be given to an independent body, revalidation should be strengthened to include an evaluation of fitness to practise, and that elected members be replaced with appointed medical members (Department of Health, 2004b). She did not recommend an increase in the proportion of lay members.

The government's proposals for future reform of the GMC and other health care professional regulators are still awaited at the time of writing. However, some reflections

²⁷ *Private Eye* had revealed the scandal earlier but this was not widely reported.

on the implications of this study for the future of professional regulation are presented in the final chapter. In the following sections of this chapter, I examine some of the main debates about the model of regulation for CAM practitioners within the policy network. I examine the prevalent and dominant ideas about protection of title, structure, dual registration, governance and entry identified in the data.

10.3 Protection of title

Fundamental to the *Urmodell* was the protection of title. This meant that unqualified practitioners could not legally present themselves as registered. The alternative option for regulating the practice of non-registered practitioners is to restrict certain practices or the use of techniques, sometimes called protection of function.²⁸

The General Osteopathic Council (GOsC) spoke publicly about the benefits that statutory protection of title would bring, “the ultimate sanction of striking a practitioner off the statutory register now has real teeth as the practitioner...will be unable to practise under the professional title of osteopath” (General Osteopathic Council, 2000b, para 416). It was also the basis of their business case for setting up the GOsC. Without protection of title there would be no compulsion for practitioners to register and therefore no guarantee of the number of members who would pay fees to the new council (Clarke, 2005, para 13). The European Herbal Practitioners Association (EHPA) and the Faculty of Homeopathy both expressed concerns that under a voluntary scheme anyone could practise and call themselves a herbal practitioner “without a day’s training” (European Herbal Practitioners Association, 2000, para 715) or a homeopath “after reading an article on homeopathy in the Daily Mail or the Mirror” (Faculty of Homeopathy, 2000, para 665). This was a familiar argument made by CAM practitioner groups about the problems of voluntary regulation (Brown, 2004). However, it should be recognised that statutory protection of title does not prohibit anyone from practising the therapy under another name as only the title is protected (see below).

The non-medical or lay homeopaths, through the Council for Organisations Registering Homeopaths (CORH), are working towards establishing a single voluntary register. The Chair, Maggy Wallace, felt that if the benefits of protection of title were properly understood by the profession they would be pursuing statutory regulation. She said that:

²⁸ Among statutorily regulated professions only dentists and midwives have protection of function.

protection of title is actually the single biggest issue and if we actually had the debate with the profession now on statutory or voluntary and people really understood that protection of title can only be achieved through statutory regulation, my personal view is that the majority of the profession would go for statutory regulation (Wallace, 2004, para 145).

As it is the new homeopathic register faces a challenge to attract registrants. It will have to set the fee at a level that practitioners are willing to pay, and ensure that its register is well publicized so that it becomes the single authoritative source to which patients turn when seeking a homeopath (Gordon, 2006).

The *Urmodell* does not offer functional closure because it does not restrict the common law right to practise medicine, and therefore its ability to protect the public from unqualified practitioners is limited. The House of Lords noted that following the establishment of the GOsC practitioners who were not admitted to the new register continued to practise under titles such as ‘osteomyologists’ or ‘cranio-sacral practitioners’ (House of Lords Select Committee on Science and Technology, 2000a, para 5.31). The limitations of protection of title are acknowledged by other state actors. Gordon Brown, the lead official for CAM at the Department, said there will always be “breakaway groups” (Brown, 2004). He questioned the feasibility of enforcing protection of title, given the lack of clarity about who was responsible for pressing charges against an unregistered practitioner and wondered “Is it bluff or is it real?” (Brown, 2004, para 471). His frank response to the problem was that:

While you can prosecute someone who uses a professional title you cannot stop them practising under a different, non-protected title. Ultimately, therefore, you just have to live with ... the rogue ones and gradually over time, as patients learn how to identify the bona fides or legitimate practitioners...the rogue ones are going to lose patients, they're going to lose support and gradually you wear them down and weed them out (Brown, 2004, para 479).

Since the interview the General Chiropractic Council (GCC) has successfully prosecuted a number of unregistered practitioners (General Chiropractic Council, 2005b; General Chiropractic Council, 2005c).

Representatives of consumers’ organisations tended to be critical of the *Urmodell*. The Consumer’s Association (CA) recognised that statutory regulation did not offer full protection to consumers because:

only the title, not the practice, will be protected, so that those who use the techniques but do not use the protected title will still be able to practise outside the consumer protection provisions of the statutorily-regulated sector (Bloomfield, 1997).

Frances Blunden, Principal Policy Adviser at Which?, went further to suggest that practitioners who had been struck off statutory registers (such as by the GMC) were able to continue to treat patients in these unregulated sectors such as CAM – “getting the same access to vulnerable people” (Blunden, 2004, para 45). Short of the police taking out an injunction, there was nothing that could be done to stop such people setting up practise as a therapist. The CA were also critical of voluntary self-regulation. They noted that voluntary bodies do not have powers to suspend therapists while complaints are investigated, nor can they stop therapists from practising if they are found guilty of malpractice (Consumers Association, 2004, para 14).

The Acupuncture Regulatory Working Group (ARWG) debated protection of function. Members decided that it was “probably unachievable” because of the problems of defining acupuncture (*vis a vis* other skin piercing modalities), and because acupuncture is widely used by practitioners who would not wish to register (Acupuncture Regulatory Working Group, 2003, para 148). Medical acupuncturists were concerned that they would be forced to dual register with the GMC and a new council in order to use the title ‘acupuncturist’ (British Medical Acupuncture Society, 2004, paras 110-112). They were also suspicious of assurances that practice would not be restricted and wanted specific mention made in new regulations that it did not restrict the right of doctors and other regulated professionals to practise acupuncture (Cummings, 2005, para 238). There was some confusion about the difference between protection of title and the protection of function among practitioners, with some believing that statutory self-regulation would make it illegal for non-registrants to practise Chinese herbal medicine (Register of Chinese Herbal Medicine, 2000, p178). It was taken as given that once herbalists were statutorily regulated they would be given exclusive rights to dispense restricted potent herbs.²⁹

Protection of title was also seen as a means of making it clearer to the public which practitioners were qualified. A well-publicised voluntary register was also believed to provide some public protection, but only if the public were educated about which registering organisation they should contact. The Department official in charge of CAM regulation stressed the importance of each voluntary registering organisation having a

²⁹ Section 12.1 of the Medicines Act 1968 provided the legal basis for herbal practitioners to treat patients following a personal consultation. In addition a list of potent herbs restricted to the use of herbal practitioners and prohibited from inclusion in over-the-counter herbal products without a full medicines license was created (SI 1977/2130) (McIntyre, unpublished) but ‘herbal practitioner’ was never defined.

communication strategy. Although she admitted such a system was “never going to be watertight” (Sidwell, 2005, para 139). The Department saw it as the duty of professional regulatory bodies to “provide high quality information that members of the public need” (Department of Health, 2000d, para 122). Although some politicians called for the government to provide the information (Parliamentary Group for Alternative Medicine, 2000, p 165; Tredinnick, 2000, p290), the lack of regulation made it difficult for the Department to be confident in the information it could provide to the public (Department of Health, 2000c, para 80).

The main focus of discussion among herbalists was over the designations to be protected. Practitioners were keen that the distinct identities of western herbalists, traditional Chinese, Tibetan and Ayurvedic medical practitioners should be preserved, and that the titles available should reflect this (Herbal Medicine Regulatory Working Group, 2003, para 231).

Debates on protection of title are partly influenced by the nature of the therapy and its history. Herbalists use of potent herbs is a well-defined practice that can be restricted, whereas it is more difficult to limit the use of dry needling given other similar uses by tattooists. Within herbalism there are a number of traditions, each eager to maintain its unique professional identity through protection of specific titles. In homeopathy and acupuncture there are a significant number of practitioners who are already statutorily regulated that wish to retain the right to use the protected titles. The use of titles and different views about the standards of training and practice required to be a competent acupuncturist were central to disagreements between the leaders of the non-medical and medical acupuncturists. These debates among CAM practitioners reflect the importance of titles for trading purposes, and their fear that they will be excluded from the economic benefits of closure. Use of a protected title also confers status and legitimacy on practitioners and is closely bound up with professional identity.

10.4 A single or joint council

The *Urmodell* is based around a single council. The alternative to regulating each therapy individually is to bring several therapies under a joint or umbrella council.³⁰

During the 1980s attempts were made to establish a multi-therapy register. The Institute for Complementary Medicine (ICM) established in 1982 administered the British Register of Complementary Practitioners Council of Complementary Medicine (Institute for

³⁰ Nurses, midwives and health visitors are regulated by a joint council, the Nursing and Midwifery Council (formerly the United Kingdom Central Council for Nursing, Midwives and Health Visitors). The Healthcare Professions Council (formerly the Council for Professions Supplementary to Medicine) is an umbrella Council with specialist committees for each of the therapies that it regulates.

Complementary Medicine, 2000). It was unable to attract the majority of CAM practitioners, and most established therapies sought to pursue a strategy of establishing a single regulatory body following indications from the government that this was their preferred approach (Association of Community Health Councils for England and Wales, 1988). In the mid-1980s the government no longer believed that CAM practitioners could unite sufficiently and indicated they would review the case for regulation on an individual basis (Trumpington, 1987).

In the early debates among osteopaths and chiropractors the Council for Professions Supplementary to Medicine (CPSM) was considered as a possible route to statutory regulation. The CPSM was set up to provide state registration to practitioners such as physiotherapists, chiropodists and radiographers working in the NHS. As the vast majority of osteopaths and chiropractors practised in the private sector (and largely do so today - see Chapter 2) the CPSM was not appropriate. Furthermore, both groups of practitioners wished to continue to operate independently of the medical profession, with the ability to diagnose and treat problems without referral or delegation of care from doctors (unlike the therapies regulated by the CPSM). Osteopathy and chiropractic were determined to retain their separate identities. The idea of pursuing statutory regulation jointly was discussed when the King's Fund Working Party was established, but it was deemed "too complicated" in terms of governance arrangements, and negotiating support from all the groups involved (Maxwell, 2005). Lord Walton went on record saying that, "the two professions were so separate in so many ways that there was no chance of having a single regulatory authority" (General Chiropractic Council, 2000b, para 497).

Osteopathy and chiropractic were supported by parliament to establish individual councils, although the differences between the two therapies were and remain somewhat opaque to the general public. Elizabeth Lynne MP (Liberal Democrat, Rochdale 1992-1997) was critical of the lack of a definition of osteopathy in the Osteopaths Bill, and said that "Only after detailed consultation was it decided that there were sufficient differences between osteopathy and chiropractic for them not to be covered by the same Bill" (Hansard, 15 January 1993). Although the government did redraft the original Bills introduced by Lord Walton, the content of the final legislation was largely based on the earlier drafts produced by the King's Fund Working Parties. So the earlier decision taken by the King's Fund to deal with the two therapies separately also influenced the process. It is unlikely that the same decision would be taken today. One official at the Department reflected on how much attitudes have changed:

I don't think that could have survived today. I mean the mood is different today...there's very much a move these days to have larger blocks of professions working together and that just wouldn't have happened today (Brown, 2004, para 175).

Having established their own regulatory body, the osteopaths favoured a single council for other CAM therapies:

the majority of the larger professions within CAM would wish to maintain their autonomy and their right to self-determination. I suspect the establishment of a credible system of self-regulation under a single body will be most appropriate (General Osteopathic Council, 2000b, para 413).

The HMRWG suggested that the GOsC and the GCC might consider joining the proposed CAM Council. The potential benefits presented were “the promotion and regulation of interdisciplinary working” and shared costs (Herbal Medicine Regulatory Working Group, 2003, para 172). For osteopaths at least the proposal was “politically appalling... not sensible at the moment” (Clarke, 2005, para 85). The GOsC noted in their formal response that, “we see that the CAM Council could potentially be extended to other, as yet, unregulated complementary alternative medicine” (General Osteopathic Council, 2004, para 9, emphasis in original). Although Norma Morris, Chairman of the GCC, accepted the logic of merging with other regulators, she maintained that:

professions are very individual and a lot of our success in getting people to register and getting chiropractors to cooperate in raising standards is because of this feeling they have of their individuality and personal recognition (General Chiropractic Council, 2000b, para 497).

The proposal to include osteopaths and chiropractors was not carried forward by the government, despite some Departmental support for the idea.

In order to speed up the process for individual therapies to gain statutory regulation the government created provisions within the Health Act 1999 which would allow them to join the newly constituted HPC, or to establish a single council using a Section 60 order (precluding the need for primary legislation). The HPC however was institutionally-bound by its predecessor and failed to broaden the criteria, or their interpretation, sufficiently for CAM practitioners to meet them (Sidwell, 2005, para 44). Both acupuncture and herbal medicine considered but rejected the idea of joining the HPC (Department of Health, 2004a, para 51). The ARWG were put off by the precondition that new groups were to have functioned as a mature profession for several years prior to application. It was felt this might mean a further delay of several years (Acupuncture Regulatory Working Group, 2003).

Ministers initially supported a single council for each therapy because they were wary of existing umbrella CAM organisations. Yvette Cooper MP, Parliamentary Under Secretary of State for Public Health, told the Lords' Sub-Committee that she "would be personally uneasy about going too rapidly towards umbrella organisations that do not have sufficient concentrated expertise or thoroughness when it comes to regulating a particular area" (Department of Health, 2000c, para 44). Because regulation of emerging CAM therapies was new the government felt it was important "to ensure that there really is the proper expertise and proper level of detail within that area" (Department of Health, 2000c, para 44). The House of Lords recommended against umbrella groups on a number of grounds, but were particularly concerned about multi-therapy practice. They suggested that:

Umbrella bodies may also give a cloak of respectability to practitioners who may have minimal training in one or more of the different therapies. They may also encourage multi-therapy practitioners who want to mix a number of different therapies without being properly trained in one or more of them (House of Lords Select Committee on Science and Technology, 2000a, para 5.67).

The government accepted the House of Lords' recommendation, stating that "The Government ... strongly encourages the regulating bodies within each therapy to unite to form a single body to regulate each profession" (Department of Health, 2001a , para 49).

The acupuncturists expressed a strong preference for a single council. The ARWG report stated that:

The Working Group has decided that the acupuncture profession would, at this stage, be best served by a free-standing statutory regulatory body for acupuncture...The regulatory process necessary to achieve this will...enable the widest take up of registration and be the most effective way of dealing with the large number of unregulated practitioners by virtue of its clarity of focus (Acupuncture Regulatory Working Group, 2003, para 168-9).

The British Acupuncture Council (BAcC) reiterated this position in response to the government's proposals to establish a shared or umbrella council. In its view a single council would:

provide the best guarantee of the preservation and enhancement of the educational standards which have characterized the development of professional acupuncture in the UK and would...have greater direct influence and control over all users of acupuncture techniques, not just the acupuncturists on its register...both the acupuncture and herbal medicine professions face significant and considerable challenges in achieving their own immediate aims for professional unity, and that for each, the creation of a coherent profession is a precondition of a successful future joint enterprise (British Acupuncture Council, 2004b, para 28).

The ARWG considered proposals from the HMRWG to establish collaborative regulation with a structure similar to that of the HPC but these were rejected in favour of a single council (Acupuncture Regulatory Working Group, 2003, para 163).

The acupuncturists objected to a joint council with the herbalists on the grounds of costs. The BAAC feared that the fees from acupuncturists would be used to offset the higher costs of regulating herbal medicines (O'Farrell, 2004, para 157), and that they would incur the costs of creating an unnecessarily large regulatory structure (British Acupuncture Council, 2004b, para 26). Interestingly, the medical acupuncture representative on the ARWG was supportive of a joint council with the herbalists primarily because he thought it would save money (Cummings, 2005, para 100). The BAAC were strongly opposed to a general CAM Council "because of the potential for stuffing everything under one umbrella". They felt that if they were grouped together with other CAM therapies that were generally viewed as inferior this would diminish their status *vis a vis* other health professions. They would be considered to be "below the salt" (O'Farrell, 2004, para 177).

Herbalists came out in favour of a shared or umbrella council. They believed it would yield economies of scale resulting in lower fees and better resources to carry out regulatory functions, enable individual professional identity and professional autonomy to be maintained, and promote work across professional boundaries (European Herbal Practitioners Association, 2004, para 9-14). The HMRWG recognised that while "separate councils promote the status and development of individual professions, they militate against interdisciplinary working" (Herbal Medicine Regulatory Working Group, 2003, para 174). It seems the concerns of traditional Chinese medical practitioners were influential in the final proposals. A shared council would give traditional Chinese medicine (TCM) statutory identity and make it easier to bring TCM practitioners into the process (Lampert, 2004, paras 24-29). The Chair of the HMRWG, Michael Pittilo was also influential. He was "Totally and utterly committed to a shared CAM Council" and "felt from the beginning

that that was the right way to go. I think it's a nonsense to have a proliferation of small individual councils" (Pittilo, 2004, para 53).

There are conflicting accounts as to whether the Department suggested that the ARWG and the HMRWG discuss the option of a shared CAM Council. Certainly, by creating separate regulatory working groups for each of the therapies, the Department of Health established a process that militated against discussion between the therapies. Nor does it appear that the Foundation for Integrated Health, who jointly established the Working Groups, had a strong view either way. Pamela Jack, Manager of the Regulation Programme, said "I don't think we had any strong views initially about whether they should be joint or single councils but the precedent was the osteopaths' and chiropractors' approach" (Jack, 2004, para 114). However, she admitted that through involvement with the groups issues such as the high fees paid by osteopaths and chiropractors, the small number of herbalists and the "TCM issue where you've got a large number of traditional Chinese medicine practitioners that practice both" led them to support a joint council (Jack, 2004, para 114).

Similar arguments appear to have shaped the government's proposals, produced by the Department, which came out clearly in favour of a shared or umbrella council. The Department favoured an umbrella council because "other therapies can be added, as and when", though a Department official admitted that she couldn't see that happening in the near future (Sidwell, 2005, para 32). An umbrella council would also accommodate traditional Chinese medicine and other practitioners, who practise both therapies, without requiring them to register with both bodies (Sidwell, 2005, para 41).

In official documents the Department highlighted the economies of scale associated with a joint council. In response to concerns from practitioners they emphasised that a joint arrangement would result in lower fees. For example the proposals state that:

the Health Departments recognise the cost benefits to practitioners of a shared Council for the herbal medicine and acupuncture professions. Representations received by the Departments suggest that the cost of statutory regulation is a key concern for practitioners, particularly those who have not been involved with the two regulatory working groups (Department of Health, 2004a, para 54).

Data on the number of practitioners registered with other regulators and their fees were used to support this position. For example osteopaths and chiropractors have 3,225 and 2,019 registrants and charge £750 and £1000 respectively. Estimates prepared by the HMRWG suggested the annual registration fee would be £262 based on a shared council for herbal medicine and acupuncture. Estimates prepared by the ARWG based on a

separate council for acupuncture practitioners suggested they would need to charge an annual registration fee of £322 per fully registered practitioner (Department of Health, 2004a, para 56).

The CHRE also came out strongly in favour of a shared council, believing it to be the best model to meet the needs of patients, the public and practitioners, to ensure the regulator has adequate resources to fulfil its statutory functions, and “to cope with emerging regulatory demands” (Council for the Regulation of Healthcare Professionals, 2004, para 25-31).

Homeopaths favoured a single regulatory body. The CORH is actively working towards establishing a single voluntary register for homeopaths, though it has suggested the homeopathy profession might consider joining a shared statutory council at some point in future (Council of Organisations Registering Homeopaths, 2004b, para 18). Commenting on the proposals for the regulation of acupuncture and herbal medicine, the CORH favoured a structure that gave each profession greater autonomy whilst “benefiting from shared services, such as offices, secretariat and computer systems” (Council of Organisations Registering Homeopaths, 2004b, para 26). The Society of Homeopaths were clear that the model of regulation should give “each grouping full representation and independent management of its regulatory and standard setting procedures” (Society of Homeopaths, 2004, para 52).

There were mixed views among existing regulators on whether therapies should be regulated by a single council or a shared council. Graeme Catto, President of the GMC, had his personal doubts about the need for a proliferation of separate councils but did not readily acknowledge that alternative models already existed. He stated:

There has to be an argument about rationalisation or at least decent cooperation and coordination between them. You simply can't have an independent regulator for every new technique or new technology that emerges (Catto, 2005, para 35).

Catto was also sceptical of the expansion of the General Dental Council (GDC) to include dental hygienists and dental practitioners. Interestingly, the nurses and midwives who have experience of a joint model were very positive about the idea of a umbrella council for CAM. Indeed, the Royal College of Nursing was one of the few organisations giving evidence to the House of Lords' Sub-Committee that supported an umbrella council (Royal College of Nursing, 2000). It gave a quite lengthy testament as to why this was a good idea, citing the following benefits: “economies of scale; sharing good practice; the patients’

perspective and potentially from the NHS point of view, it might be easier to relate to one organisation” (Royal College of Nursing, 2000, para 547).

The United Kingdom Central Council on Nursing, Midwifery and Health Visitors (UKCC) was ahead of other statutory regulators in its ideas about collaborative regulation:

One thing the Council is increasingly coming round to is the view that because...healthcare practitioners are working in teams rather than individuals, the notion of overarching legislation to cover regulation would seem to be a logical and sensible step. How far in the future that might occur, one does not know (UKCC, 2000b, para 586).

Finally, the Royal College of Midwives recommended that the CAM Council adopt a similar system as that in place for nurses and midwives, “enabling practitioners of different therapies to remain appropriately regulated in respect of their individual skills and competencies, but also facilitating the pooling of resources for cost-efficiency” (Royal College of Midwives, 2004, para 56).

The Consumers’ Association has espoused the benefits of both a single register for each therapy, and latterly the virtues of an umbrella CAM Council, on the grounds that they make it easier for patients to find out which practitioners are ‘safe’ and which ones are not (Consumers Association, 2004, para 21; Coe, 2005, para 28). The idea of a single federal voluntary regulator is also promoted by consumer organisations as a means of enhancing informed consumer choice (Coe, 2005, para 55). Interestingly the Foundation for Integrated Health, which originally supported the development of single registers is now promoting a federal voluntary regulator. The Manager of the Regulation Programme admitted that:

As time has gone on ... I think we can see that there may be opportunities for more integration of the different groups that would lead to more...synergy or cost saving (Jack, 2004, Para 318).

She went on to justify the investment that had been made in developing single voluntary registering bodies for each therapy. Jack argued that:

before you can bring the different professions together under one roof, you have to have a profession in the first place and so...there is something about the people within the groups going through this process that helps in the formation and development of an organised profession (Jack, 2004, para 323).

The question at the heart of these debates is whether separate regulators are necessary in order to maintain separate identities, whether separate identities add value to the care and

treatment of patients (Clarke, 2005, para 83), or whether they enhance the status and reputation of practitioners. An individual council for each therapy was favoured by practitioners, keen to preserve their autonomy, whereas government was keen to promote the idea of a shared council, in the interests of minimising the number of regulators. Those practitioners who practise more than one CAM therapy, such as traditional Chinese medical practitioners, only supported the shared model if having their own regulator was not feasible.

10.5 Dual registration

Multi-disciplinary practice is generally becoming more common in health care. The boundaries between professions are increasingly blurred. Yet the system of professional regulation characterised by the *Urmodell* is based on professional silos. The premise was that a doctor, once trained, was competent to do what a doctor did. There was no definition of the scope of activity or what competencies were required to perform those activities. Consequently doctors, and other statutorily regulated practitioners, have been able to practise CAM without training. The onus has been on individuals to prove they are competent. The *Urmodell* gave doctors scope to define and redefine the boundaries of their practice. These boundaries have shifted over time and some activities have been ceded to other professionals.

Dual registration has existed to a limited extent between dentistry and medicine (e.g. maxillofacial surgeons), and there are a handful of osteopathic doctors with dual registration of the GMC and the GOsC. Yet there are currently no formal mechanisms laid down which govern how regulators cooperate in cases regarding fitness to practise concerning dual registrants. Graeme Catto, President of the GMC, did not seem unduly concerned at this lack of formality and felt there were no significant difficulties in linking with other regulators and “making sure we don’t fall over each other” (Catto, 2005, para 24). He did then go on to cite two cases where “people have fallen through the crack” (Catto, 2005, para 26). Gynaecologist Rodney Ledward was struck off the medical register for serious professional misconduct but “popped over to Ireland and continued to work as a pharmacist”, while Richard Neal, also a gynaecologist, had been barred from practice in Canada but was able to register and practice for 14 years in the UK before being struck off (Dyer, 2000).

CAM practitioners frequently practice more than one modality. Multi-therapeutic or multi-disciplinary practice poses particular challenges for regulation. Transregulatory issues also arise because there is widespread practise of CAM therapies among statutorily regulated

professionals. As was discussed earlier, the preference for a joint or umbrella council was in part driven by a desire to facilitate multi-therapeutic practise. From the practitioners' perspective transregulatory arrangements are important because they determine what standards need to be met, grant the right to use a title, and may require multiple fees to be paid.

The ARWG proposed that statutorily regulated practitioners would join the register but that their existing regulator would remain their primary regulator (i.e. for disciplinary matters, educational standards, revalidation and continuing professional development). This distinction between registering and regulating functions had not been made before and it was not clear how it would work in practice. The government was clearly opposed to any changes to the current arrangements and stated that it did "not favour dual registration and will therefore not make it a requirement for healthcare practitioners who work across professional boundaries." (Department of Health, 2004a, para 112). It went further than this and actively discouraged practitioners from dual registration claiming that "practitioners who choose to follow this approach will need to recognise the risk of creating confusion about which regulatory body would respond if their fitness to practise were called into question" (Department of Health, 2004a).

Suggesting that practitioners chose their regulator has major consequences that the BAaC, at least, felt had not been fully explored (British Acupuncture Council, 2004b, para 72). It is not clear whether the Department envisaged a "hierarchy of regulators" in which some are "more equal than others", i.e. some regulators could require registration in order to practise the discipline (British Acupuncture Council, 2004b, para 72). The alternatives would be to allow dual registration but define who decides which regulator will handle the fitness to practise and under what circumstances, to have a single disciplinary mechanism for all health care practitioners, or to create legal access to a protected title for specialist registrants e.g. 'medical acupuncturist' or 'homeopathic doctor' under existing statutory councils. The EHPA rightly recognised that:

This question about which Council a doubly-qualified practitioner...should register with and to which Council that practitioner's registration fee is payable, is an as yet unresolved question that goes far wider than the CAM sector since multidisciplinary working is becoming a feature of the NHS (European Herbal Practitioners Association, 2004, para 72).

The medical acupuncturists' main interest was in maintaining the right to use the title 'acupuncturist' (see above). At the time of the House of Lords' Inquiry, the British Medical

Acupuncture Society (BMAS) were resistant to dual registration: “We believe...that medical practitioners should still clearly be regulated by the GMC and we would feel uneasy about having to register as acupuncturists under any other statutory organisation” (British Medical Acupuncture Society, 2000, para 996). They were loathe to have to register with a body which they felt would be dominated by non-medical acupuncturists, to have to meet educational standards which did not take into account prior medical training or required additional training, or to have to pay two sets of registration fees. But during the discussions of the ARWG it became clear that in order to be able to promote themselves as acupuncturists they would need to be registered with the new regulatory body.

Proposals were developed that accommodated their demands. The BMAS would retain the ability to set educational standards, its members would pay a reduced fee to be listed on the acupuncture register, and would be able to use the title ‘acupuncturist’. The Department’s opposition to dual registration presented them with the possibility of “being faced with prosecution for continuing to practise in name as an acupuncturist” (British Medical Acupuncture Society, 2004, para 110). Consequently, the BMAS has been lobbying the Department of Health to alter its proposals so that this situation is avoided.

The medical acupuncturists found allies among the medical homeopaths. Although dual registration is not yet an issue for medical homeopaths it would arise in future were homeopathy to become statutorily regulated. In commenting on the proposals for dual registration the Faculty of Homeopathy, which represents medical homeopaths, states:

There should be no dual regulation but dual registration would be open to anyone who was regulated by any of the other statutory regulating bodies...as long as they are also able to demonstrate the required level of education (through membership of an accredited body such as the BMAS or Faculty in the case of homeopathy) (Faculty of Homeopathy and British Homeopathic Association, 2004).

Lay acupuncturists opposed the government’s proposals on different grounds. They feared that without dual registration there would be no clear standards governing the use of acupuncture techniques by statutorily regulated professionals (British Acupuncture Council, 2004b). Currently, statutorily regulated healthcare professionals (such as doctors, nurses and midwives) who practise CAM therapies are encouraged to self-regulate their practice. They are left to judge for themselves whether they are competent, and must take personal responsibility for ensuring they are adequately trained (General Medical Council, 2000a, p96; UKCC, 2000a, p227).

The herbalists did not support dual registration but wanted the new council to be given statutory powers to set educational standards, accredit courses, and provide continuous professional development for other statutorily regulated professionals wishing to practise herbal medicine and acupuncture (European Herbal Practitioners Association, 2004, para 52). The EHPA claimed that such an approach was in line with the Bolam test³¹ that expects a professional to meet standards that are in line with a responsible body of opinion (European Herbal Practitioners Association, 2004, para 26). It was also supported by the government, which thought the CAM Council would “provide professional leadership to all healthcare professions in the area of standards for the practice of herbal medicine and acupuncture” (Department of Health, 2004a, para 111). The role would also involve giving expert input in fitness to practise cases on issues relating to the practice of herbal medicine and acupuncture.

The Consumers’ Association also believed that doctors, nurses and other health professionals who practise CAM modalities should be registered with the proposed CAM Council. The argument made in support of this was that “the public will...trust their doctor if they are doing this [acupuncture or herbal medicine], and they’ll assume that they’re competent, properly qualified, meeting all the right standards” (Blunden, 2004, para 53). Dual registration would require practitioners “to meet standards of professional knowledge and competence” and “ensure that they had proper training” (Consumers Association, 2004, paras 11 & 45). The Prevention of Professional Abuse Network (POPAN) also supports dual registration because “going to, say, the GMC, to complain about an acupuncturist, is counter-intuitive” (Coe, 2004, para 70).

The frequency of multi-therapeutic practice among CAM practitioners has brought transregulatory issues to the fore in designing regulation. The desire among statutorily regulated practitioners to not only continue to practise CAM therapies (as they can without registration) but also to use the protected titles and promote these activities has added a further complication to the issue of dual registration.

10.6 Governance

The *Urmodell* is based on a largely paternalistic model of regulation: ‘doctor knows best’. Control of regulation is delegated to the profession, hence self-regulation. Professions dominate the council and committees and carry out the functions of the regulator, such as

³¹ The Bolam test defines the standard of care required of a doctor or any other person professing some skill or competence. The case was that of *Bolam v Friern Hospital Management Committee* (1957). The judge in giving direction to the jury said negligence could be determined as follows: “A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art”.

setting standards, adjudicating in fitness to practise hearings, and so on. During the past 15 years the *Urmodell* has come under increasing scrutiny from the public, the media and the government. There is a growing consensus about the need for an adjudication function independent of the profession, and for increased lay representation on council and committees. Professions are now expected to share control with lay representatives. CAM practitioners are no exception.

The composition of the GMC has changed considerably since its establishment (Chief Medical Officer of England, 2006). Although data from different accounts are not entirely consistent, the broad trends are similar. The GMC had 24 members when it was established, of whom the majority (18) represented the universities and Royal Colleges while the remainder were professionals appointed by the Privy Council (6). An amendment in 1886 allowed general practitioners to elect five doctors by postal vote. The first lay member was introduced in 1926 (Irvine, 2006). The Council almost doubled in size to 47 members by 1974 (Chief Medical Officer of England, 2006). Following the Merrison Committee and the Medical Act 1978 the GMC expanded to 93 members, of whom just seven were lay. The majority were elected medical members (Irvine, 2006). By 1995 lay membership had increased to 25. They sat alongside 25 appointed medical members and 54 elected medical members (Allsop and Mulcahy, 1996, p75). Reforms implemented in 2003 reduced the size of the Council to just 35 members, of whom 40 percent were lay members. All the medical members were elected, and the university representatives were in the minority.

When the GOsC was created it was heralded as a model of modern professional regulation. According to a Department of Health official “It is a model not only for CAM professionals but other healthcare professionals to consider” (Department of Health, 2000d, para 36). Malcolm Moss MP, sponsor of the Bill, said it “broke new ground” and called it “a landmark for future legislation” (Hansard, 15 January 1993). The GOsC’s governance structures reflected the government’s views of best regulatory practice at the time (Hansard, 15 January 1993). A Department of Health official, commenting on the Osteopaths Act 1993, stated that “There is much greater emphasis on accountability to the public and transparency in the way in which the scheme works and the need to win public confidence” (Department of Health, 2000d, para 36).

The Osteopaths Act 1993 included provisions for there to be a greater proportion of lay representatives on the GOsC than were on the GMC at the time. In fact 12 out of the 24 seats on the Council were elected by the profession from among registered osteopaths,

thus retaining 50 percent representation.³² The government also maintained the tradition of having medical interests represented on the governing bodies of other health care professions by requiring at least one lay member to be a registered medical practitioner. The Act also made registration conditional on the registrant being in good physical and mental health, created three committees to carry out the fitness to practise procedures (the investigating committee, the professional conduct committee and the health committee), required the Council to publish an audited set of accounts annually, and made registration subject to post-registration training.

The government had already set out their intentions in *Supporting doctors, protecting patients* that professional regulatory bodies should be open, transparent, accountable and fair (Department of Health, 1999). In their response to the House of Lords' Report the government re-stated this view: "professional self-regulation works best when it operates as an open and transparent partnership between the profession, patients and the wider public" (Department of Health, 2001a, para 49). These ideas which informed some of the recent reforms to the GMC also shaped the proposals for the composition of a CAM Council for acupuncture and herbal medicine.

The HMRWG report recognised that lay representation on all committees was important and recommended that 40 percent of the Council would be made up of lay members, and that there would be at least two on each statutory committee and professional advisory group established by the Council (Herbal Medicine Regulatory Working Group, 2003, para 170). The Department suggested that the new body should:

work in partnership with employers, education providers and other regulatory bodies for health and social care professionals and services; consult registered practitioners, employers, education providers, patients and the public in making or varying policy, standards and rules; have regard to the differing considerations affecting the herbal medicine and acupuncture professions and the individual traditions within the professions (Department of Health, 2004a, para 77).

The government also proposed that the Chair of the CAM Council be a lay person, in order to "ensure that the Council is well-equipped to carry out its fundamental function of safeguarding the health and well-being of patients and the public" (Department of Health, 2004a, para 90). The government believed that an independent Chair would be better able

³² In addition to the 12 elected osteopath members eight members were appointed by the Privy Council and one by the Secretary of State, with three members appointed by the Council's Education Committee (representing the interests of training institutions).

to arbitrate between different interests and traditions among CAM practitioners. It claimed that:

A lay Chair will...have equal regard for the differing considerations affecting the herbal medicine and acupuncture professions and the individual traditions within the professions. This impartiality will be particularly important if the Council is required to consider any issues on which the individual professions or traditions may not be in agreement (Department of Health, 2004a, para 90).

The suggestion that there should be not only significant lay representation but also that a lay member should chair the Council is a major departure from the *Urmodell* and the principles of self-regulation. Perhaps the level of fragmentation among CAM practitioners necessitates such a role.

Nigel Clarke, originally appointed as a lay member to the GOsC before becoming its Chair, explained the benefits of lay representation during oral evidence to the House of Lords. He said:

...the main thing that lay members have brought is independence...independence has been very important as the profession has come together from a disparate group of regulatory bodies who do not always seem to have had a lot of love for each other previously. Lay members do not have that background and cannot be conceived as partisan in relation to one previous regulatory body or another (General Osteopathic Council, 2000b, para 431).

The independent chairs of the regulatory working groups were vital to prevent all out battles between factions within herbal medicine and acupuncture. Michael McIntyre, President of the EHPA, said that the Chair acted as the “referee” and the lay people were the “linesmen” during discussions of the HMRWG (McIntyre, 2004, para 69). According to the Manager of the Regulation Programme at the Foundation for Integrated Health, the acupuncturists also worked well together under the ARWG and they recognised the benefit of having an independent lay chair and lay people (Jack, 2004, Para 94). Yet Michael Pittilo, who was Chair of the HMRWG, expressed a personal and contrary view: “I think we’ve gone overboard on lay representation and I’m very, very worried about that in all areas” (Pittilo, 2004, para 251).

Another criticism of lay representation is that lay members do not necessarily represent the consumer or public interest. Often lay members are representatives of other healthcare professions or educational interests. Both the BAoC and the EHPA were worried that lay representatives would be drawn from health and social care professions. According to the BAoC this “creates the very real possibility that orthodox western medical professionals

could in theory represent a block vote of almost half of the Council membership” (British Acupuncture Council, 2004b, para 60). Instead they wanted to see “people of broad ranging skills and backgrounds”, especially patient support groups and consumer groups (British Acupuncture Council, 2004b, para 61) This view was shared by the EHPA who said “lay members should have varied backgrounds so that lay representation is not weighted in favour of orthodox medicine” (European Herbal Practitioners Association, 2004, para 60).

A key preoccupation among CAM practitioners, reflecting earlier debates within the orthodox medical profession about representation for general practitioners on the GMC, was that regulatory bodies should reflect the diversity of practice. They felt the governing structures should represent fairly the different traditions within a particular therapy, for example herbal medicine. The composition of the proposed CAM Council became a major point of contention in the government’s consultation on the statutory regulation of acupuncture and herbal medicine. The different traditions within CAM have also clamoured for their own representatives in the governance structures of regulators. Smaller groups wanted to be fully represented, while more established practitioner groups felt this would give disproportionate voice to these groups. The BAAC recognised it would not be appropriate to have representatives of each tradition within the Council as this would undermine the governance role of the Council (British Acupuncture Council, 2004b, para 57). The EHPA suggested that when the number of registered practitioners in a tradition reached a defined number they would become eligible for representation on the Council.

Although the *Urmodell* assumes professional dominance of the governance arrangements and control of regulatory functions, in practice the early GMC was dominated by educational interests and those of the Royal Colleges. Most professional members were appointed by the Privy Council. They were not elected representatives of the profession or of elements within it. When the GMC introduced an annual retention fee in the early 1970s it sparked demands for representation from doctors, many of whom refused to pay. The Merrison Committee of Inquiry was appointed primarily to resolve this issue, and paved the way for the Medical Act 1978 which expanded the Council and created a majority of elected professional members (Irvine, 2006). The recommendation of Dame Janet Smith was to replace elected members of the GMC with appointed members reversing the policy of the 1970s. This suggestion has been taken up by the Chief Medical Officer in his recent report (Chief Medical Officer of England, 2006) Recommendation 43). It would clarify the

role of a professional association (which represents the interests of practitioners) and that of a regulator (which should operate in the public interest with professional input).³³

CAM is fragmented and practitioners have a tendency to retrench into factions when disagreements arise. Lay representatives and independent Chairs have been essential in assisting CAM practitioners to reach a consensus on regulation. It therefore seems appropriate that any new regulatory bodies should also have strong lay representation. The government's response to the consultation on the future of health care professional regulation will hopefully clarify standards of best practice with regards to the composition and governance of regulatory bodies. The future of professional regulation is discussed further in the concluding chapter.

10.7 Controlling entry to the register

When a register is first established transitional arrangements are usually put in place in order to facilitate the entry of existing practitioners and those in training to enter the register. New rules cause disruption, particular to those who entered the profession under earlier rules, so compensation or transitional arrangements are needed, in order for regulation to be deemed fair (Wolfson, Trebilcock et al., 1980). Once the register is up and running the main route of entry is via graduation from accredited courses. During the transitional phase there are a number of options open to a regulator to assess the competence of new registrants, such as through examination, a personal professional portfolio, or accreditation of prior learning or experience.

Much of the discussion by CAM practitioners focused on the issue of 'grandparenting' (or 'grandfathering'). This was variously defined. The ARWG defined grandparenting as "Options for assessing and registering existing practitioners" (Acupuncture Regulatory Working Group, 2003, para 48). Others defined 'grandparenting' as providing automatic entry to the register for existing practitioners (Society of Homeopaths, 2004, para 142; Wallace, 2004, para 165; Clarke, 2005, para 41). All agreed that explicit standards should be defined and individual registrants should demonstrate that these had been met (Society of Homeopaths, 2004, para 142).

Opinions within the GOsC were divided on how to establish the new register. Nigel Clarke, who sat on the shadow Council, recalled that:

³³ The Osteopaths Act 1993 and the Chiropractors Act 1994 blurred the distinction between a professional association and a regulator by including promotion and development of the profession among the Councils' statutory duties. The Royal Pharmaceutical Society of Great Britain also has a dual role although it is likely that this will be separated in the near future.

The first question of Council, the fundamental question, was: did we register people on the grandfather clause or did we try and establish some other mechanism for determining safety and competence for the first register. And that was a momentous decision (Clarke, 2005, para 35).

Interestingly, it was the osteopathic members rather than the lay members who wanted to make people prove their competence (Clarke, 2005, para 37). The decision was taken that “there would not be a grandfather clause...we would not just take anybody who called themselves an osteopath before” (Clarke, 2005, para 41). They put in place a set of “tight criteria” against which individual applicants were judged on the basis of a personal portfolio. Clarke described the system as “almost a form of revalidation from scratch” (Clarke, 2005, para 41). If people did not pass the first stage of the application process there was an interview and an assessment of clinical competence. If registration was still refused the applicant had the right of appeal. This proved a lengthy and expensive process and some practising osteopaths were refused registration.

Practitioners were keen that registers be inclusive. The ARWG argued that “inclusivity is the best guarantee of standards and public safety” (Acupuncture Regulatory Working Group, 2003, para 317), and the EHPA stated “The process of Registration should be made as inclusive and helpful as possible” (European Herbal Practitioners Association, 2004, para 94). In particular, practitioners stressed the need to reach out to those who were not currently registered, such as traditional Chinese medical practitioners, who use acupuncture as part of their practice but were not involved in the ARWG. The ARWG recommended:

that in order to achieve the greatest level of inclusivity on the new Register, there will need to be sufficient time to identify and inform practitioners working outside the current voluntarily and statutorily regulated bodies of the existence of the Register. This will be a considerable challenge, since there are many practitioners in this group for whom English is not their first language (Acupuncture Regulatory Working Group, 2003, para 317).

On the other hand, standards need to be high enough to ensure that registered practitioners are capable of safe practice. “In order to ensure that the principle of inclusivity does not lead to a dilution of standards, the qualifying period will be only one factor in determining entry to the Register” (Acupuncture Regulatory Working Group, 2003, para 320). The ARWG proposed the following arrangements:

a comprehensive application process from which individual assessment levels can be determined for each registrant; a practice history identifying both current and past practices aimed at meeting a qualifying standard for entry to the register, provisionally set at three years practice from the last five years; a comprehensive peer-reviewed self-audit process for both safe clinical practice and professional conduct (Acupuncture Regulatory Working Group, 2003, para 319).

Other checks on language competence, criminal record, child protection registers, and physical and mental health were also discussed as part of the screening and registration process.

Surprisingly, the government's consultation document said very little about how entry to a new register would be determined. It recommended that the following categories of practitioner be eligible for registration under 'grandparenting' arrangements: i) herbal medicine and acupuncture practitioners in practice prior to the opening of the register, regardless of their affiliation to any professional association; ii) herbal medicine and acupuncture practitioners in training in the UK during the transitional period; iii) practitioners who trained overseas and wish to begin practising in the UK during the transitional period. The primary requirement for registration was that practitioners prove that "they have been engaged in the lawful, safe and effective practice for three out of the five years prior to the opening of the Register (or its part-time equivalent)" (Department of Health, 2004a, para 150). No proposals were put forward as to how this might be assessed.

The government's proposals set the bar for entry lower than the Working Groups had recommended. According to the BAAC:

Both Working Groups...agreed that 'three years from five' would only be a part of the requirement and that there should be a 'burdle' of some sorts to filter out those who do not meet the agreed standards (British Acupuncture Council, 2004b, para 103).

The government only suggested that applicants demonstrate additional training or experience or take a test of competence if they were unable to satisfy the 'three out of five' criteria. The experience of the osteopaths (described above) indicated that consultation on the transitional arrangements would be important to ensure support from practitioners. Yet there was "no mention...on the methods of processing applications or description of the process and cost of identifying what counts as safe, legal and effective practice" (British Acupuncture Council, 2004b, para 103).

The CORH has not yet published the details of its grandparenting arrangements for the new voluntary register for homeopaths, but has rejected automatic entry. It is likely,

however, that members of existing registers will find it easier to meet the criteria for entry (Wallace, 2004, para 165). The preference appears to be to have a simple system of initial entry with registration subject to agreed continuous professional development requirements. Over time this would ensure that everyone on the register is up to date and safe to practise.

There was clearly a preoccupation among practitioners with grandparenting arrangements. Clarke illustrates the point well:

the single most important thing about regulation is actually who you let on the register in the first place. And what standards they have to display to get there and what must do to maintain their standards. Those are the things that really matter (Clarke, 2005, para 85).

Many CAM practitioners have had little or no formal education, particularly those who learned traditional medicine as apprentices, but may have practised for years. Their livelihood and ability to continue to operate as a business depends on successful registration. Such fears are in part generated by the experience of osteopaths, where some practitioners were not admitted to the register. Leaders of practitioner groups on the other hand want to raise the bar and ensure a high level of training among registrants. This may be tied up with their desire for enhanced professional reputation and economic closure. Despite entry criteria being critical to the effectiveness of regulation in protecting the public, the government left the setting of the standards for entry to the professions. The government's proposals for acupuncture and herbal medicine actually set a lower threshold for entry than that suggested by practitioner groups.

10.8 Other ideas about professional self-regulation

The ideas examined in the previous sections are all concerned with how to organise professional self-regulation. Debate mainly focused on how aspects of the medical model could be adapted and applied to CAM practitioners. There was almost no discussion of alternative models to professional self-regulation by CAM practitioner groups or the state. The House of Lords' Select Committee was largely silent on how to regulate CAM practitioners. It considered there to be two options, statutory self-regulation and voluntary self-regulation. It briefly considered the different routes to statutory regulation, via a single Act or under the Health Act 1999. General regulations that apply to CAM practitioners were cited in the report having been laid out in the Department of Health's written evidence. But these regulations were not the subject of discussion. The possibility that these could be strengthened or changed was not countenanced. The focus was firmly on voluntary versus statutory self-regulation.

This suggests a lack of ideas in the policy stream, to use Kingdon's term. The following section analyses the ideas put forward about professional self-regulation and its alternatives by orthodox medical practitioners, consumer representatives and academics.

10.8.1 *Orthodox medical practitioners*

Existing regulators supported the idea of professional self-regulation for CAM practitioners. In a sense to question this model would bring into question their own right to self-determination. The UKCC admitted their bias: "as a regulatory body, we would say that self-regulation works, would we not?" (UKCC, 2000b, para 587). Graeme Catto, President of the GMC, admitted "It is perfectly clear if you look at the medical model, that it is no longer sufficient, never was" (Catto, 2005, para 14). He went on to say "I don't think there is an alternative here. If there is an alternative nobody else has come up with it." (Catto, 2005, para 94). Despite recognising the weaknesses and failings of the *Urmodell* there appeared to be a lack of ideas about any alternatives.

The focus of debate among regulators was on improving the *Urmodell*, not its abolition. One alternative that was briefly discussed was external regulation. This was seen as complex, however, and it was thought would lead to conflicts of interest, especially where the state is involved in the financing and delivery of services. Catto believed that:

If you don't go for some kind of...professionally led regulation then you have got to think what you would put in its place. And if you start going down that line you have got to have external regulation. All the evidence is that external regulation becomes increasingly complex (Catto, 2005, para 7)

He therefore concludes that:

[the] future of health care regulation for the foreseeable future is secure until someone puts up a better model and they haven't. So changing the existing one and making it more fit for purpose is where we should be putting our efforts (Catto, 2005, para 100).

Others were also staunch defenders of self-regulation. Lord Walton, Chair of the House of Lords' Sub-Committee and a former president of the GMC (1982-1989), declared that he would defend professional self-regulation "to the death", though it should be "carefully monitored by the lay public and by parliament" (Walton, 2005, para 172). He went on to laud self-regulation, quoting Lord Hailsham:

that great Lord Chancellor ...[who] said that professional self-regulation is one of the glories of a civilized society but that such professional self-regulation must invariably take account of informed lay opinion and advice. I agree (Walton, 2005 , para 171).

Among orthodox medical practitioners self-regulation was seen as the model of regulation, albeit tempered by lay representation to ensure public accountability. External regulation by the state was rejected. Institutional blinkers meant that few alternatives were seriously considered.

10.8.2 Consumer representatives

The Consumers Association criticised the Department for its narrow viewpoint, suggesting it was influenced by the professionals and was not interested in meeting its stated objective of public protection. Frances Blunden, Principal Policy Adviser at Which?, said that:

Part of the problem...is they [the Department of Health] have taken very much a professional stance; it's about bringing the profession together, getting the profession to work when actually they sometimes need to turn it on the head and say what do we need to protect the public? (Blunden, 2004, para 71).

Representatives of consumers organisations were keen that any system of regulation should make it easier for consumers to obtain information, make complaints, and contribute to the development of codes of practice. The CA described a system of regulation that would, in their opinion, meet the interests of consumers:

A consumer agenda here might include moves towards a single register for each therapy with agreed core competencies that all must have, externally-accredited training institutions and courses, the involvement of users both in drawing up codes of practice and in monitoring compliance with them pro-actively, truly independent elements within the disciplinary mechanisms and greater openness about their findings. And it would be good to see therapies take on board the idea of an independent Ombudsman, preferably one covering the whole sector (Bloomfield, 1997, para 58).

They did not make a blanket suggestion for greater lay representation on professional councils and committees, but suggested that the involvement of lay or independent people in the disciplinary procedures could help complainants feel that their case had been properly heard (Bloomfield, 1997, para 26). The National Consumer Council made similar recommendations in its more general report on health care regulation (National Consumer Council, 1999).

Interestingly, the CA suggested strengthening professional codes of practice. The CA proposed that an adequate code for CAM practitioners should cover:

the legal obligations of practitioners, the limitations on treatment that a particular therapy can offer or claim to offer, expected professional conduct towards patients, how therapists should relate to medical practitioners and what kind of information should (and what claims should not) be given to patients. It should include requirements to keep good records, to preserve patient confidentiality, to have decent premises, to advertise services and fees in a reasonable fashion and to deal with patients' complaints properly. It should also be clear that practitioners can be disciplined if they fail to comply with the code (Bloomfield, 1997, para 21).

They proposed that codes should be the subject of public consultation to ensure both public and professional support, and suggested that given the many common elements a combined code of practice for CAM practitioners could be developed (Consumers Association, 2004, para 71).

Models of regulation which create a single point of contact for consumers were also welcomed. For example, ideas such as an independent Ombudsman and a single independent complaints procedure for all health professions were proposed by consumer organisations (Blunden, 2004, para 145; Coe, 2005, para 9).

The Consumer's Association were one of the few organisations to propose an alternative to professional regulation. They suggested that other consumer protection measures might be more appropriate to protect patients such as "through trading standards agencies, the police, those kinds of consumer protection approaches" (Consumers Association, 2000, para 832). These ideas put forward by consumer representatives were not widely discussed by other stakeholders.

10.8.3 Academics

One potential source of new ideas entering the policy stream is academia. As we saw in the analysis of the policy network in the previous chapter, most academics remained on the periphery with one or two exceptions. Julie Stone, through formal roles at the Foundation and the CHRE, operated within the core of the policy network. She is also the only academic in the policy community to have contributed ideas to the debate about how to regulate CAM practitioners. Others contributed to the wider debate, in Kingdon's terminology the 'problem stream', rather than putting suggestions for regulation in to the 'policy stream'.

Unlike most others in the policy network, Stone took up the challenge of trying to "devise appropriate models of regulation capable of responding to a very different therapeutic relationship" (Stone, 1996, para 8). Her idea (with Matthews) of 'patient self-responsibility'

was picked up by other members of the policy network, particularly consumer representatives (Stone and Matthews, 1996). The idea is that “The public also have a role in protecting themselves by ensuring that they consult suitably regulated practitioners” (Stone, 2000, p287). The government’s role would be to ensure that consumers have access to reliable information about qualifications and voluntary registers on which to base their choice of practitioner.

This idea was picked up by the House of Lords’ Inquiry which took evidence specifically on information provision, and resonates with the views of consumer organisations who have called “for the government to accept some responsibility for the information gap and produce similar guidance for consumers” (Bloomfield, 1997, para 61). The Department have actually implemented a number of policies to improve consumer information on CAM, including commissioning *Complementary Healthcare: a guide for patients* from the Foundation for Integrated Health (Pinder, 2005), establishing a national electronic library for health on CAM, and including information on certain therapies on NHS Direct online.

Stone also suggested some additional safeguards to enhance public protection: “there should be a mandatory requirement for all registering bodies within a therapy to inform other such bodies when they have erased a practitioner from their register” (Stone, 2000, p287). She also recommended that personal liability insurance should be mandatory for practising CAM practitioners (Stone, 2000, p284). As was seen in Chapter 3 mandatory disclosure and liability insurance could increase the ability of consumers to make informed choices and to be compensated in cases of negligent care. Largely these strategies are complementary to systems of voluntary or statutory professional self-regulation. They do not present radical alternatives.

10.9 Discussion

The medical model of regulation, despite widespread criticism, has dominated policy discussions about how to regulate CAM practitioners. Debate has focused on adjustments to the *Urmodell* rather than alternatives to it. The GOsC and the GCC were modelled closely on the GMC. Osteopaths and chiropractors were heavily involved in drafting the Private Members’ Bills which became the basis for legislation. Although the government redrafted the Bills, the model implemented did not fundamentally deviate from the *Urmodell*. Some adjustments were made, including increased lay representation, public reporting, mandatory continuing professional development (in other words revalidation), and published standards of practice. Similar provisions were included in subsequent reforms of established health care professions.

Perhaps more surprising is that the Acupuncture Regulatory Working Group (ARWG), when asked to develop a model of regulation in 2002, proposed a model for a General Acupuncture Council that for all intents and purposes was a replica of the GMC. There were one or two innovative aspects to the proposals, in particular a register of medical acupuncturists which would permit use of title but not require dual registration with the General Acupuncture Council. It also took on board some of the reforms either proposed or implemented at the GMC, such as increased lay representation, changes to the fitness to practise procedures, etc.

The Herbal Medicine Regulatory Working Group (HMRWG) was more in tune with government thinking. It proposed two alternative models that were akin to the NMC or the HPC: a joint council with acupuncture, or else an umbrella council under which acupuncture and herbal medicine would initially be regulated with provisions for other CAM therapies to join in future. This model of collaborative regulation was designed to benefit from economies of scale and scope and according to estimates would be more cost-effective, thus reducing the fees charged to practitioners. Even so, it is difficult to argue that this was a radical departure from the *Urmodell*. Under either structure the profession would be responsible for setting standards of education and practice, control entry to a register and use of protected titles, hold at least half of the seats on the Council and most committees, and implement disciplinary procedures. So even in 2003, by which time more cases of misconduct by doctors had come to light and were under investigation or subject to public inquiry, the Working Groups proposals largely reproduced the medical model of professional self-regulation.

Organisational decision-making has been likened to a garbage can into which many problems and solutions are dumped or a policy soup (Cohen, March et al., 1972; Kingdon, 1984). According to Kingdon (1984), decisions depend on the convergence of a number of streams. The analysis of policy debates about models of regulation for CAM practitioners suggests that there was a lack of ideas about other regulatory options in the policy stream. It could be argued that there was a lack of policy imagination. Those regulatory strategies that were proposed were not readily picked up by politicians. For example ideas to strengthen consumer protection measures or to establish an independent system of complaint did not resonate with the central players in the policy network, many of whom were medical practitioners. Consequently there was only one dominant idea: professional self-regulation.

Other theories of the policy process focus on the importance of bureaucratic routinisation or on historical institutionalism. They generally favour incrementalism. As has been noted

elsewhere, “Policy-makers are rarely if ever presented with a blank state, and the field of professional regulation is no exception” (Wolfson, Trebilcock et al., 1980, p188). Policy-makers appear to have prioritised regulatory approaches with which they were more familiar, that would face less opposition from organized professional interests and that fitted with existing institutional structures, because they perceived these to be easier to implement.

For officials in the Department of Health the medical model of regulation was perhaps an easy off-the-peg policy option. When Department officials were asked to come up with a design for the implementation of statutory regulation for acupuncture and herbal medicine, the policy ideas were shaped by precedent. Firstly, most of the officials in the team were familiar with the institutional models of statutory regulation that existed for other health care professionals. Secondly, the decision was taken in response to recommendations by the House of Lords’ Sub-Committee that were framed in terms of statutory self-regulation. Finally, the regulatory working groups were asked to examine the options for achieving the successful statutory regulation of the herbal medicine/acupuncture profession as a whole. In other words, there was never a time in the policy process when alternatives to statutory self-regulation were considered. This suggests that the model of professional self-regulation was the only idea. This view was shared by Julie Stone, Deputy Director at the CHRE:

One might even go as far as to suggest it showed a bit of a want of imagination that that was the only regulatory model up for grabs. But in fairness it was the only regulatory model for ‘real’ professionals, real health care professionals, that had been on the table since the 1850s (Stone, 2005b, para 32).

It was not a matter of bureaucrats choosing an easy and familiar policy option from among alternatives. It seems the officials responsible for professional regulation within the Department were trapped in a 19th century paradigm.

The fact that policies were modelled on existing regulators and informed in their design by the experience of other professions may be an important reason as to why more radical alternatives were not considered. Existing arrangements for professional regulation appear to have coloured the views of those in the policy network and restricted the regulatory options considered. Representatives of orthodox medicine appeared institutionally bound by their own experience of regulation. Those in the system seemed to find it difficult to think outside the box. Although legislative changes under the Health Act 1999 meant that other CAM practitioner groups were unlikely to follow exactly the route taken by osteopaths and chiropractors, it was felt that “we can learn from what they did, we don’t

have to do exactly the same thing” (Jack, 2004, para 364). Acupuncture and herbal medicine both examined the osteopaths’ and chiropractors’ experience of setting up a register (Acupuncture Regulatory Working Group, 2003, para 394).

The structures and arrangements in place for orthodox health care professions were also used to inform the ideas about CAM practitioners. For example, changes to the fitness to practise procedures of the GMC were the basis for those proposed for the CAM Council (Department of Health, 2004a, para 187), while the structure of the HPC and the NMC provided a template for a shared CAM Council (Brown, 2004, para 357; Stone, 2004, para 31) and the federal voluntary structure proposed by the Foundation (Jack, 2006, para 34). The example of the relationship between the GMC and the GDC was cited when discussing transregulatory arrangements (Cummings, 2005, para 67-70). Even when developing voluntary systems, CAM practitioner groups were eager to track developments in statutory regulation and be mindful of some of the problems that were encountered (British Acupuncture Council, 2000, para 765; Society of Homeopaths, 2000b, para 687; Wallace, 2004, para 157; Stone, 2005b, para 32).

The models implemented and those proposed for the regulation of CAM practitioners differ only incrementally from the medical model of professional self-regulation. The government could have strengthened existing measures or introduced new regulations of a different nature, but it didn’t. Although it is not possible from the analysis here to say conclusively why other models of regulation (such as those outlined in Chapter 3) were not considered, it does appear that professional self-regulation was the one that was most familiar to those involved in the policy network. Despite the wider political events, which could be characterised as a crisis in professional regulation, the medical model of regulation remained the dominant idea. External shocks were not sufficient to precipitate a paradigm shift or third-order, major non-incremental change (Hall, 1993).

The final chapter draws together the major themes of the study, and concludes with a discussion of the implications of these findings for regulatory policy in the UK and for health policy research in general.

11 CONCLUSION

11.1 Introduction

The study has focused on the regulatory process that led to the decisions to statutorily regulate certain CAM practitioners in the UK. Although previous research has examined the professionalisation of CAM practitioners (Saks, 1994; Cant and Sharma, 1996) it has done so mainly from the perspective of the practitioners. Recently published research in Canada examined the views of government officials on the role of the state and whether CAM should be integrated with conventional medical care (Kelner, Wellman et al., 2004b). Here I have employed four different analytical approaches to explain why the regulatory process for CAM has taken the form that it has. These different approaches have enabled the role of practitioners, the state, other policy actors and ideas to be examined.

In this chapter I review how useful the different analytical approaches have been in answering the research questions posed at the beginning of the study: why are some CAM therapies statutorily regulated and others not, and why was the model of professional self-regulation chosen to regulate CAM practitioners? I discuss some of the challenges and limitations encountered during the research process and explore the implications for further research. Finally, the aim of the study was to inform policy discussions about regulation of CAM practitioners and the future of professional regulation in the UK. Reflections on what insights can be drawn from the study about these policy issues are discussed in the final section of this chapter.

11.2 The analytical framework revisited

11.2.1 *Demand theories*

Demand theories of professionalisation (summarised in Chapter 5) predict that statutory regulation is the culmination of activities by practitioner groups in pursuit of occupational closure. In other words, professionalisation occurs because occupational groups demand it. This is in contrast to supply theories of professionalisation (see below), whereby occupational groups ‘supply’ professionalisation in response to external pressure (e.g. from the state). Demand theories were largely able to explain the cases of osteopathy and chiropractic, and to a lesser extent that of herbal medicine, where practitioner groups came together to establish themselves as a unified profession with a common goal of achieving

statutory regulation. However, the theories were not applicable in the cases of acupuncture and homeopathy. The study's findings suggest a number of limitations to the explanatory value of demand theories of professionalisation.

Firstly, statutory regulation is not the inevitable culmination of professionalisation. Theories of professionalisation connected with functionalist approaches suggest that whether occupational groups achieve statutory recognition depends on how advanced they are in the transition from occupation to profession. All the therapies examined here were well advanced on the path towards professionalisation. Yet neither the acupuncture profession nor the homeopathy profession explicitly expressed a desire to be statutorily regulated, despite being developed as professions in other respects.

Secondly, income maximisation is not the primary motivation for occupational groups to seek occupational closure. The leaders of CAM practitioner groups recognized that there might be economic benefits arising from increased public confidence, a greater willingness among GPs to refer patients, and possible changes in NHS purchasing policies. The experience of chiropractors and osteopaths, however, coloured the expectations that other CAM practitioners had of the economic benefits of statutory regulation. Chiropractors and osteopaths, once statutorily regulated, enjoyed some increased referrals from primary care, but they were not integrated into the NHS as had been expected. Among CAM practitioner groups social status and reputation were perceived as more important than the economic benefits of closure. Protection of title was seen as crucial to the profession's ability to maintain its reputation (among the public and with conventional health care professionals). It meant practitioners whose practice brought the profession into disrepute could be disbarred from using the professional title.

Thirdly, a profession or defined occupational group is not a unitary actor (see Greer, 2004, pp48-50 for an interesting discussion of the three faces of the medical profession). The views of leaders or elites among occupational groups are rarely representative of the majority of practitioners. Demand theories of professionalisation often portray the occupational group as having a unified interest. Grassroots CAM practitioners were concerned with maintaining their autonomy as independent practitioners, in contrast to the leadership's interest in enhancing the standing of the profession. Practitioners believed that standards of training and practice would stifle creativity and innovation. Furthermore they were opposed to being required to pay large registration fees. Such extreme polarisation may be unique to CAM. CAM practitioners are by their nature a non-conformist bunch who are suspicious of any suggestion of government interference in their practise. At times they have seen regulation as part of a conspiracy by the leaders of their own profession, the

orthodox medical profession and government to stifle or subvert the practice of CAM. This study did not examine the views of practitioners directly but was limited to the perceptions of leaders. It is possible that the leaders of practitioner groups distorted or exaggerated the views of practitioners, and such stark differences in opinion might not exist in reality.

Finally, statutory regulation may not necessarily result from the mass mobilisation of members of an occupational group. Given the supposed benefits of occupational closure, theory would expect practitioners to form interest groups to lobby for statutory recognition. Statutory regulation was not even an explicit objective of professionalisation for acupuncturists. Where regulation was professionally demanded, in the cases of osteopathy, chiropractic and herbal medicine, it did not come about as a direct result of mass mobilisation. As the personal network analysis demonstrated (discussed below), policy entrepreneurs from within CAM formed strong alliances with others outside CAM. The only example of professional mobilisation was among the members of the British Medical Acupuncture Society (BMAS) in response to the Lords' Report. Although there was a public campaign mounted in opposition to the European Union (EU) Directive on Traditional Medicinal Products which involved herbalists, the issue at stake was the availability of unlicensed herbal products and not the regulation of herbalists *per se*.

Demand theories have further limitations. By focusing on the actions of occupational groups they overlook the constraints under which occupational groups operate. In particular they ignore the government's influence on how successful an occupation is in pursuance of their goals. Demand theories conceive of the state as passive and neutral in matters of policy. This study found that the state played a much more active role in the professionalisation and regulation of CAM practitioners.

11.2.2 *Supply theories*

Supply theories of professionalisation predict that professionalisation is a response by occupational groups to state demands. In the cases of acupuncture and herbal medicine the study found that these theories provided a strong explanatory framework. Even in the cases of osteopathy and chiropractic where the state's role was largely passive, it still shaped the context in which practitioner groups made their claims to statutory regulation. The study found that government-wide approaches to regulation influenced the approach taken, and as these changed so did the approach to the regulation of CAM practitioners. The study identified three main phases.

In the first period, from 1985-1999 under the Conservative government and during the early years of the Labour government, the interests of the state were aligned closely with professional interests. CAM practitioners organised themselves and were subsequently 'rewarded' with statutory regulation. This partly appears to confirm the hypothesis derived from the demand theories of professionalisation that the state responds to the demands of professional groups. However, statutory regulation was only introduced if practitioner groups met certain criteria set out by the state. The criteria shaped the approach pursued by osteopaths and chiropractors. Another explanation for what occurred, therefore, is that the professions were actually responding to the demands of the state. Thus supply theories of professionalisation have some explanatory value during this period. But compared to how involved the state was in the professionalisation of acupuncture and herbal medicine (see below), the state was largely passive during this phase and relied on the practitioners to 'get their house in order'. The government's activities at this time were limited to generating data and information to help them understand the CAM market better (Thomas, 1995; Mills and Peacock, 1997; Luff and Thomas, 1999).

It appears that the state's approach to the regulation of CAM practitioners shifted from a passive approach to a more proactive one around the time of the House of Lords' Sub-Committee on Complementary and Alternative Medicine in July 1999. The Lords' Sub-Committee's call for evidence included a question on regulation and risk:

Are there areas of complementary and alternative medicine where lack of regulation causes unacceptable risk to the public? Are there practicable forms of regulation that would provide protection without unduly restricting patient choice? (House of Lords Select Committee on Science and Technology, 2000b).

The government's decision to introduce statutory regulation for acupuncturists and herbalists, following the recommendations of the Lords' Report, was based on a concern to protect the public from the risks associated with toxic herbal medicines and contaminated acupuncture needles. It did so although there was almost no evidence regarding the scale of the problem. Internationally there were a few well-publicised incidences of contaminated herbal medicines (laced with heavy metals, animal derivatives or restricted active ingredients such as steroids), and adverse reactions caused by the toxicity of particular herbal products due to lack of standardisation and quality assurance processes during production. Between 1999 and 2003 the government was pro-active in supporting the formation of unified professions among acupuncturists and herbalists, upon which the successful implementation of statutory regulation depended.

Having justified its action in relation to acupuncture and herbal medicine on the basis of direct physical risks (from prescribing and dispensing herbal medicines and skin piercing with needles), the government could not defend any proposals which did not accommodate traditional Chinese medical practitioners (who combine both activities). Their inclusion has resulted in delays to the implementation of statutory regulation for acupuncture and herbal medicine.

Homeopathy, unlike herbal medicine and acupuncture, was not seen to pose a direct risk to human health because the dilutions of homeopathic medicines are so great. The orthodox medical profession claimed homeopathy posed serious indirect risks because it operated as a discrete clinical discipline, and therefore might result in patients not seeking conventional medical treatments. Interestingly, although the Lords' suggested homeopathy should be considered for statutory regulation on these grounds, the government did not accept these arguments. The government chose instead to encourage homeopaths to improve their system of voluntary regulation.

The decision to use risk as the criteria for determining which CAM therapies to regulate also reflected wider government policy. Although a regulatory state had been emerging in the UK since the 1980s, it was in the 1990s that the regulation of risk increased. In the 1980s financial regulators were created as part of the process of privatisation.³⁴ In the 1990s new regulatory agencies were created to monitor and enforce standards in public services.³⁵ In health, agencies with regulatory functions were created to ensure the safety, quality and cost-effectiveness of health services (e.g. the National Patient Safety Agency, the Commission for Health Improvement, the National Institute for Clinical Excellence, etc.). The UK government, like its counterparts in other countries, felt the need to respond to growing public concerns about the hazards of modern society (characterised as the risk society by Beck, 1992). Public scares, fuelled by the media, surrounding the risks to human health posed by BSE-infected beef, mobile phone masts and toxic waste dumps resulted in the introduction of new regulations.

More recently there has been a backlash against the growth of risk regulation. It is not possible to eliminate risk, but trying to do so may lead to a diminution of responsibility. The most recent publication from the Better Regulation Commission states that:

³⁴ For example the creation of the Office of Telecommunications (1984), the Office of Gas Supply (1986), the Office of Electricity Regulation (1989) and the Office of Water Services (1989) were all part of privatisation acts.

³⁵ For example the establishment of the Office for Standards in Education (1993).

We want to challenge the easy assumption that governments can and should manage all risks. We want to see a new understanding between government, regulators, the media and the public that we all share a responsibility for managing risk and that, within the right circumstances, risk can be beneficial and should be encouraged (Better Regulation Commission, 2006).

In the final phase, from 2003 up to the present, the dominant concern has been to ensure the cost-effectiveness of regulation. The principles of better regulation set out by the Better Regulation Task Force (proportionality, accountability, consistency, transparency and targeting) have been applied to the regulation of CAM practitioners.

The idea of better regulation originally emerged in response to worries about whether regulation placed an unnecessary burden on small and medium size enterprises, thus putting a brake on economic growth. The costs of regulation to the state and the burden on the public sector have also come under increasing scrutiny (Public Sector Team Regulatory Impact Unit, 2001). Objections to the growth of regulation have resulted in a series of government reviews (Hampton, 2005). Since 2002 regulatory impact assessments must be completed for “all policy changes, whether European or domestic, which could affect the public or private sectors, charities, the voluntary sector or small businesses” (Better Regulation Executive, 2006). Departments are encouraged, as part of an assessment, to consider alternatives to command and control regulation (i.e. legislation) such as no intervention, information and education, self-regulation, or incentive-based structures. The fact that other CAM practitioners are pursuing voluntary self-regulation as an alternative to statutory regulation rather than as a step towards it, is clearly driven by the government’s agenda to minimise new legislation. Indeed, the government is actively supporting the development of voluntary self-regulation for other CAM practitioners by subsidising the costs of the process (through a grant to the Foundation for Integrated Health).

The state has demanded different things of different practitioner groups at different times. In each case studied here the professional groups have responded to the demands made upon them (to ‘get their house in order’, to professionalise, to unify and to reach consensus on standards, etc.). It appears then that the supply theories of professionalisation provide a useful explanatory framework for understanding the development of the regulation of CAM practitioners. But there are also some limitations to supply theories of professionalisation.

Firstly, the findings here suggest that the state interest is not fixed or deterministic but that it changes over time. The state’s interest in the regulation of CAM practitioners ebbed and

flowed. Some of the supply theories believe that the interests of the state are based on economic and structural factors which are largely unchanging. Findings here suggest it is more dynamic. Although the study did not directly seek to explain what influenced the state, some factors have been identified.

The growth in the use of CAM and in the number of practitioners providing CAM partly contributed to CAM's rise up the policy agenda. The popularity of CAM with the public meant there were greater demands for its availability on the NHS, but also potentially more opportunity for people to be harmed. Public health scares in the media about contaminated and toxic herbal medicines, and general fears about blood borne infections associated with needle contamination, heightened the focus on the risks of CAM. External factors also played a role. For example proposed changes to EU legislation, with major implications for the availability of unlicensed herbs in the UK and the legality of herbalists' practise, prompted a public campaign orchestrated by commercial interests including health food stores and herbal manufacturers. Changes in government thinking about business regulation also had a significant bearing on regulatory policy in other areas of government, and the health sector and CAM were not immune from this. This study found the state's interest to be malleable and dependent on a whole host of external and internal political factors.

Secondly, there is not a single state interest but several competing state interests. The study found that the state acted paternalistically to protect the public but was also concerned with protecting consumers' rights to choose and practitioners' freedom to practise. In an effort to promote the public interest the government was faced with the option of restricting access to unlicensed CAM medicines and unlicensed CAM practitioners. But it also believed it was against the public interest to over-regulate and place limits on consumer choice and freedom to practise. The state has a tricky balance to strike between professional interests, public protection, consumer choice and its own self interests. As the balance between these competing interests changes so too does the approach taken by the state with regard to regulation.

Finally, the supply theories view the state as a single homogeneous entity when in fact it has many facets. The term 'state' can be used to encompass the legislature, the executive and the judiciary. Ultimately it is comprised of individuals such as MPs and peers, Ministers and government officials, etc. By treating the state as homogenous, supply theories of professionalisation may fail to recognise the tensions between state actors and the impact on the policy process of competing interests. Policy is also shaped by discussions and debates beyond the formal legislative process which are ignored if analysis only focuses on

the actions of the state. Personal policy network analysis may be one possibility of addressing this deficiency.

11.2.3 *Policy networks*

Political science research in health care has tended to focus on the influence of the medical profession. Despite the vast range of different views that exist not only between but within well-established corporatist bodies such as the British Medical Association (BMA) the medical profession is often portrayed as a single interest group. The nature of the CAM policy network demanded a different analytical approach. Personal policy network analysis was used to examine the role of individuals, each with a variety of formal and informal affiliations and some with a long-standing interest and involvement in the issue.

CAM is not the stuff of high politics. It does not feature on the agendas of Ministers or in Prime Minister's questions. It does not consist of highly mobilised coalitions of organised interest groups. The CAM policy network consists of a small group of influential individuals, policy entrepreneurs and advocates who built strong alliances with civil servants and others from within the medical profession, statutory regulators and parliament. Perhaps the most unexpected individual found at the core of the policy network was HRH the Prince of Wales. Although Prince Charles is known to be a public advocate of holistic medicine, the analysis revealed the extent to which he is actively involved in promoting the issue of CAM and its regulation privately.

The analysis was helpful in illuminating the central role that individual policy entrepreneurs from within CAM played in the policy process. The findings here support political theories which give individuals a central role in the policy process (see Chapter 4). In osteopathy, chiropractic and herbal medicine there were individuals, sometimes but not always in positions of formal leadership, who engaged with others in the policy network and actively promoted the profession. Their energy and enthusiasm appear to have driven forward the regulatory process. These were not charismatic leaders who were able to mobilise mass support from practitioners, but rather entrepreneurs who were able to capitalise on their personal contacts and affiliations to pursue particular policy objectives. Despite the focus on policy entrepreneurs and policy brokers (Kingdon, 1984) in the theoretical literature on policy process there has been little empirical analysis of their role in shaping health policy.

In any policy arena civil servants are an important audience for policy advocates. There were two civil servants who had a long-standing involvement in issues of CAM regulation, one at the Medicines and Healthcare products Regulatory Agency (MHRA) and the other at the Department of Health. They both knew the stakeholders and their peculiarities well

in their respective policy areas. They were also known to the leaders of the CAM practitioner groups. A challenge for anyone wanting to influence policy and have their ideas heard and considered is knowing who to talk to on the inside. For those outside the civil service it can be quite impenetrable and yet access is crucial. Individuals from CAM practitioner groups were at an advantage, having established an on-going dialogue with government officials.

Reorganisation at the Department of Health in 2003 resulted in the responsibility for CAM regulation moving to the branch responsible for professional regulation. Consequently policy on CAM regulation had to compete with other more pressing priorities. Further reorganisation in 2004 resulted in there being no civil servant with full-time responsibility for CAM, which left CAM practitioners without anyone on the inside who understands them. This has further changed the dynamics of the policy network. The government may yet introduce legislation to regulate acupuncture and herbalists, but the final legislative proposals will probably be influenced more by wider ideas about regulation than by specific proposals advocated by the CAM policy network. This shows how contingent the policy process is on the strength of the individual relationships that exist between those within the state (e.g. civil servants) and members of policy networks and communities.

Traditionally the medical profession has been the dominant interest group shaping health policy. Although not central to the analysis here, the study found that CAM has some powerful allies within orthodox medicine. These alliances were clearly important to those therapies that successfully gained regulation, namely osteopaths and chiropractic. For example, senior figures from the orthodox medical profession were involved with the King's Fund Working Parties, the Prince of Wales's Initiative on Integrated Health, in supporting the Private Members' Bills, the House of Lords' Sub-Committee, and as trustees of the Foundation for Integrated Health. These individuals brought legitimacy to the claims of CAM practitioners. Yet there remain divisions within the medical profession over the regulation of CAM practitioners.

Some doctors are of the opinion that the government should not 'regulate rubbish', as this would give legitimacy and status to unproven CAM therapies and might increase the likelihood of it receiving NHS funding. Others believe that regulation is needed in order to stop patients getting the 'wrong treatment': anything, as they see it, which a CAM practitioner provides. During evidence sessions of the House of Lords' Inquiry parts of the medical profession were keen to emphasise the indirect risks associated with homeopathy and called for its regulation. Some therapies are more acceptable to the orthodox medical profession because the body of knowledge on which they are based has more in common

with allopathic medicine. For example, there is a plausible scientific explanation for the effect of acupuncture connected with endorphin stimulation and the active ingredients within herbal medicines are the basis for modern pharmaceuticals. In contrast, controversy remains surrounding homeopathy. Leaders of the medical profession are disparaging of a therapy for which they believe there is no scientific basis (Baum, Ashcroft et al., 2006).

Personal policy network analysis was useful for illuminating the policy process surrounding CAM practitioner regulation, and the role of individuals within it. There were also a number of limitations. Firstly, although the role of individuals was clearly identified as being important, it is not possible to claim that regulation resulted from their actions. Personal policy network analysis may therefore be more useful as a descriptive framework than an explanatory one. Secondly, it does not allow the contribution of a particular policy advocate or entrepreneur to be measured or weighted. For example, was it the enthusiasm of Simon Fielding, an entrepreneurial osteopath, or the support of the Prince of Wales that accounted for the osteopaths' success in gaining statutory regulation? Whereas in some interest group analysis the number of members or the amount of financial resources are used as proxies for influence there was no objective measure of influence within the personal policy network analysis used in this study. Instead the researcher's judgement was relied upon to interpret information on the number of affiliations and to determine the strength of individual's relationships with other members of the policy network. Thirdly, the approach gives prominence to the leaders of organisations, who tend to be most actively involved with civil servants. This means little is known about the views of practitioners. In CAM the level of fragmentation and disunity within practitioner groups means the views of leaders are unlikely to be representative of their members. However, the personal policy network approach makes no claims that the views of individuals are representative. Finally, as a methodology it relies heavily on attribution by interviewees and by the researcher. In this study the aim was not to fully specify every member of the network at a particular point in time but to identify the main actors involved. Mapping based on interviews and documents was used to identify potential candidates for inclusion. Their inclusion and the position of individuals towards the core or periphery of the network relied on an assessment of their formal position in relation to the policy at a particular point in time. Thus the scope of each network map was limited by the time period to which it related and the focus of policy activities depicted. Future research studies could be more explicit about the inclusion and exclusion criteria used for determining network membership.

I would expect personal policy network analysis to be useful in a policy arena that is low profile, isolated and somewhat fragmented. Such an arena would have few organised corporatist interest groups, individuals would occupy positions in several organisations, and relationships would be fluid. Further empirical research is needed to test my hypothesis that the approach adopted here is applicable to other policy domains which share similarities to the CAM policy network. In a different policy arena where interest groups are more unified this approach might not be appropriate.

In conclusion, personal policy network analysis combines the strengths of personal interaction approach and formal network analysis. It allows an examination of both the inter-relationships between actors and also their formal affiliations, both of which are important to a fuller understanding of a particular policy's genesis and development. Personal policy network analysis has illuminated an important dimension of the policy process: that is, individuals matter.

11.2.4 *Ideas and institutions*

Policymakers may pursue different regulatory strategies depending on their understanding of how appropriate or effective different regulatory tools are (they have many at their disposal, as outlined in Chapter 3). They may also chose to implement those regulatory strategies through different institutional arrangements. In order to address the second research question - why did the regulation of CAM practitioners take the form that it did - the analysis drew on theories that posit that ideas are central to policy-making. Ideas can take different forms. In periods of normal policymaking the adoption of new ideas will often only result in incremental change. For example, policymakers faced with a particular problem will select from among alternative policy options (ideas) in the 'policy stream' (Kingdon, 1984). According to Hall (1993), policymakers operate within a policy paradigm. He defines this as:

a framework of ideas and standards that specifies not only the goals of policy and the kind of instruments that can be used to attain them, but also the very nature of the problems they are meant to be addressing (Hall, 1993, p279).

The presence of this framework of over-arching ideas, similar to an ideology, limits the flow of ideas to those that are consistent with the paradigm.

The study found that neither CAM practitioner groups nor state actors appear to have considered alternative regulatory tools in any systematic way. The discussions were largely limited to whether self-regulation should be enforced, that is backed by legislation to make

registration mandatory in order to use a protected title, or not. The *Urmodell* of professional self-regulation was the dominant idea. This suggests that it would take a 'third order change' for the government to shift from self-regulation to a consumer protection approach, or to adopt one of the other regulatory tools. A few ideas did circulate in the policy network about other strategies, such as improving consumer information about CAM practitioner's associations, mandating personal liability insurance, and using other incentive based mechanisms such as subsidising accredited education courses. If policymakers were operating in a policy paradigm of self-regulation it would explain why these ideas were not widely taken up. Another explanation would be that policymakers simply lacked the knowledge or imagination of how other regulatory tools might be applied.

Historical institutionalists would argue that the lack of alternatives is because policy is constrained by existing institutions, in this case professional regulators. Theories of bureaucratic routinisation on the other hand would suggest that because civil servants are used to dealing with professional regulators, it is easier for them to continue with a model that is familiar. Interest group theorists would argue that the alternative ideas are associated with less influential interest groups or individuals: those who support the dominant idea of professional self-regulation are also those with the loudest voice.

Although alternatives to self-regulation were not extensively considered, ideas about the institutional and organisational arrangements for implementing professional self-regulation were widely debated. The King's Fund working parties on osteopathy and chiropractic were set up to determine whether there was a case for statutory regulation for each therapy. The draft bills produced were largely modelled on the Medical Act, but there were some important differences. For example the Osteopaths Bill proposed significant lay representation on the General Osteopathic Council, regular public reporting to ensure public accountability, and revalidation and revised fitness to practise structures to ensure standards of practice were maintained. These ideas subsequently led to changes to the organisation of statutory health care professional regulators beyond CAM, such as the General Medical Council (GMC).

At the time proposals were being developed for the regulation of acupuncture and herbal medicine other regulatory strategies were given almost no attention. The Regulatory Working Groups were set up with the purpose of examining the options, but they limited their considerations to the structure and design of a professional regulator. At this time concerns about the costs of regulation prompted the HMRWG to propose an option to establish a joint council with the acupuncturists. The government's proposals for

acupuncture and herbal medicine favoured an umbrella council under which other therapies could be regulated in future. These ideas are concerned with organisational structures, but do not question the fundamental approach to regulation.

Ideas about regulation more generally from outside health care also shaped policy. The state's ideas about risk were important to the decision to regulate acupuncture and herbal medicine. The analysis using the supply theories of professionalisation (see Chapter 8) highlighted the importance of ideas about risk and regulation to the way the state approached the issue of regulation of CAM practitioners. Latterly the paradigm of professional self-regulation has been challenged by the paradigm of better regulation. Because most CAM practitioners operate as small businesses, government had to assess the economic impact of regulation and minimise the regulatory burden on practitioners. This meant that the proposal to establish a joint or shared CAM Council for acupuncture and herbal medicine was promoted because it was a cost-effective option. Ideas of better regulation also influenced the policy decision as to whether to regulate other CAM practitioners at all. In order to minimise unnecessary regulation, and to stop over-regulation, a different approach to the regulation of CAM practitioners emerged which favoured collaborative regulation, voluntary regulation and consumer information.

Although not explicitly part of the analytical framework applied in the other chapters, ideas appear to play an important role in all aspects of the policy process. The analysis in Chapter 10 examined the ideas that were being debated about the form regulation should take. It was unexpected that ideas also had value in explaining which therapies were subject to regulation (analysed in Chapters 7-9). State-centric theories, such as supply theories of professionalisation, have been criticised for neglecting ideas. The analytical framework could benefit from further refinement to incorporate the observation from other policy analysis that the "flow of ideas is an important dimension of the process in which policy is made" (Hall, 1993, p290). This finding suggests that future health policy research examine not only the role of actors but also of ideas within the policy process.

11.2.5 Integrating the analytical frameworks

The different components of the analytical framework have each illuminated a particular aspect of the policy process in relation to one or more of the different CAM practitioners groups examined here. How do these components fit together? Are there inter-relationships between them? Can a synthesis provide further insights into the policy process?

Reflecting on the findings of the research presented here it is possible to identify ways in which each of the different elements of the analytical framework interact and inform each other. For example the level of passivity/activity of the state provided opportunities for CAM practitioner groups to be more active in demanding statutory regulation. As previously noted, the state created the policy space into which CAM practitioner groups were able to place their demands. The criteria and expectations set by the state provided the basis on which the osteopaths and chiropractors made a successful case. Conversely, the state is the audience for demands by professional groups. Professionalisation can occur on a voluntary basis without interaction with the state, but if a profession seeks closure through statutory regulation then it necessarily brings it into contact with the state. In this study the osteopaths and chiropractors needed the support firstly of MPs and subsequently of government in order to successfully realise their ambitions for statutory professional regulation. Analysis of professionalisation in future could benefit from integrating both the perspectives of demand and supply theories of professionalisation.

Furthermore, the relative influence of professional representatives and state actors within the policy networks reflects to some extent the level of passivity/activity of professional groups and the state in general. For example, during the early phase when the state was passive the personal policy network had professionals at the core. These individuals were effective in creating momentum and support for the osteopaths' and chiropractors' demands among politicians and within government. As the state became more active the role of civil servants within the personal policy network increased in importance. Whether professionalisation is demanded by the profession or supplied in response to the state's interests appear to influence the membership and the level of influence different actors have at different times. Personal network analysis can also help to illuminate further the dynamics at play in the policy process, complementing the demand and supply theories of professionalisation. For example, personal policy network analysis revealed the extent to which individual professionals, rather than organised corporate interests, were driving the process of professionalisation. It showed how leaders of the profession were not necessarily acting as representatives but rather as policy entrepreneurs. Similarly personal policy network analysis revealed the heterogeneity of state interests and the importance of the continuity of relationship with particular civil servants on the 'inside'. Later in the policy process the interactions between the state and professional groups became more formalised, though the efforts of individuals continued to play a crucial role in the progress that these groups made in agreeing a system of statutory regulation. Personal policy network analysis added a further layer of interpretation to the policy events examined in this study.

The role of ideas was examined in Chapter 10. This component of the analytical framework was used to examine the research question about the model of regulation adopted, rather than which therapies were statutorily regulated. Yet as discussed above, ideas were also important in shaping the state's actions, the activities of different practitioner groups and the membership of the personal policy networks.

For example, as the idea of risk became more important to the state in determining which therapies should be regulated, it resulted in the acupuncturists being drawn into the process and homeopaths being sidelined. Interpretations of risk led to the demands of some professionals being given greater prominence than others. Finally, the imperative for the state to act in the face of risk meant the policy process was less open to influence by individuals within the personal policy network at this time. It appears that ideas can either facilitate or restrict whether the claims of particular groups are considered, and the ability of different individuals to influence the policy process.

During the latter phase of the study the state's position in relation to CAM practitioners was heavily influenced by ideas that held sway across government, in particular the ideas of risk-based regulation and better regulation. The priority became minimising the burden of regulation on the state and ensuring regulation was proportionate to risk, rather than the elimination of risk at all costs. The force of this idea, as well as the wider review of professional regulation, resulted in the introduction of statutory regulation of acupuncturists and herbalists stalling. The ideas about regulation held by professional groups (examined in Chapter 7) suggest that the lack of consensus about the benefits to the profession prevented unified action to lobby for statutory regulation in the case of homeopaths. Thus ideas were significant in shaping both the demands of professional groups and the state's response to them.

The explanatory value of each of the components of the analytical framework appears to vary over time and between cases. Thus by re-examining the same data using a number of different analytical lenses we are able to build up a richer and deeper understanding of the policy process and how it changes.

11.3 Research questions and methods revisited

One always has the benefit of hindsight at the end of a research project to consider how one might have done it differently. A number of choices had to be made about case selection, data sources, and the process of analysis (see Chapter 6). These choices all shaped the final study. Here I reflect on the strengths and weaknesses of the research design and methods.

11.3.1 Case selection

The story of CAM regulation has not been a straightforward one to reconstruct. There are a plethora of therapies that are usually classified as CAM, but many therapies do not see themselves that way. Some would rather define themselves as being complementary and not alternative. Some, such as osteopaths and chiropractors, do not define themselves as either ‘complementary’ or ‘alternative’ to medicine. The use of terminology here is significant. The fuzziness of the boundaries between conventional medicine and CAM means any discussion of the regulation of CAM practitioners requires careful definition. Here the study was limited to five therapies – acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy.

The therapies selected were chosen because they are the most popular and because they were at different stages in the regulatory process. On a spectrum of therapies they are, however, some of the best established, most widely recognised and most accepted (at least by the public if not by the medical profession). Crystal therapy is often the example used when one wants to illustrate the quirkiness of some CAM therapies. It certainly lies at the other end of the spectrum from acupuncture. Limiting the cases to five was a necessity: any more would have rendered the task unmanageable given time and space constraints. The five therapies chosen are not typical of CAM as a whole, however. This means generalising the findings to all CAM practitioners is difficult.

Beyond the therapies examined here there are others that are widely practised and where discussions about regulation are taking place, such as aromatherapists, Bowen therapists, cranial and cranio-sacral therapists, massage therapists, naturopaths, reflexologists, Reiki practitioners and yoga therapists. The debates are largely confined to the practitioner groups at this stage. Analysis of internal discussions within these therapies would be interesting, particularly to examine in greater depth issues identified in this study such as differences between leaders and members, the presence of policy entrepreneurs, and what if any external allegiances they are building. These other cases would not, however, have provided the opportunity to analyse the state’s perspective or interactions with a wider set of actors.

11.3.2 Sampling

The fragmented nature of CAM means there are many competing organisations and interests within each CAM therapy. The main players in the medical profession are familiar to most people. Consolidation means there is a single dominant professional association, the BMA, a single registering body and regulator, the GMC, and specialist educational and

professional interests represented by the Royal Colleges. In CAM the playing field is more crowded. As shown in Chapters 4 and 7, professional associations have been established by graduates of different private schools which often teach a particular approach to the therapy. Splinter groups have been established following disagreements among members. Specialist bodies have been established to represent particular traditions, such as Ayurveda. Consolidation has taken place to some extent, but the voluntary nature of this process means that no sooner than some of the established bodies agree to cooperate or indeed formally merge then there are new groups breaking away. In addition, CAM is practised by statutorily regulated health care professionals such as doctors, nurses, midwives, etc. Given the extent of such practice, particularly in acupuncture and homeopathy, these groups and the issues they raise were included in the study. This complex array of organisations can leave one dizzy at times, reeling at the many acronyms and frequent name changes (see note on terminology).

The plethora of different stakeholders and interest groups meant the sampling approach had to be narrowly specified in order to identify a manageable number of interviewees. Given my interest in the policy process my priority was to identify those individuals who were engaged with policy debate about the regulation of CAM practitioners. The use of snowballing as a sampling technique starting with the lead civil servant enabled me to identify key informants. However, this approach may have resulted in the exclusion of some views, particularly of minority groups that do not have access to or interaction with civil servants. Furthermore, such an approach limited the extent to which opposing views were heard. Although directly asked about ‘enemies’ as well as ‘allies’, interviewees named few individuals who they regarded as sources of opposition. Finally, it is difficult to know whether the same list of interviewees would have been generated had I interviewed someone other than the civil servant first. With this sort of sampling one has to start somewhere but remain mindful of the potential bias this might bring to the sample. On reflection the civil servant was probably well placed, having interacted with a range of people from different therapies over a number of years. Had I begun with the Chair of a CAM practitioner organisation, whilst they would have been familiar with individuals within their own therapy they might not have been able to name individuals from other therapies. Given my interest in understanding how relationships between members of professional associations and state actors shaped the policy process it was important to ensure both were represented in the sample.

11.3.3 *Data analysis*

Using a mix of inductive and deductive approaches to data analysis enabled theory to be informed by the accounts of those involved and to test established theories presented in the literature on professional regulation. However, such an approach can encourage code proliferation.

The use of a qualitative software programme (NVIVO) provided a useful means of organising data, and was a powerful tool to aid the retrieval of qualitative data. The decision not to use coding to generate quantitative data on the number of mentions meant that it was not possible to convey the strength with which particular views were held. However, the software did enable patterns to be analysed by type of stakeholder or type of therapy. Overall, there were significant benefits of using the software to handle large amounts of documentary data.

Code proliferation remains a particular risk when doing qualitative research as a lone researcher. Working as a sole researcher meant that it was not possible to cross-check interpretations or coding reliability. In this situation the importance of clear definitions for each code was essential. In the initial phase of analysis I created a lot of codes and subcodes which had to be consolidated before the final phase of analysis. During this period of consolidation I was able to reflect on the key themes that were emerging from the data and to use theory to shape the final analysis. The time period over which the research was conducted meant this was possible. In more time sensitive projects and where multiple researchers are involved a more structured and limited coding schema would be preferable.

11.3.4 *Personal network analysis and mapping*

In writing up research it is usual to present the process as linear. While it might appear from the order of the chapters presented here that the personal policy network was an *a priori* theoretical framework, this adaptation of existing theories in fact developed during the data collection and analysis when it became clear that the role of individuals was significant. If one were to design a research study in which one applied personal network analysis *a priori* the method of sampling might well be different from that employed here.

Personal policy networks were mapped during the analysis (see Chapter 9). This led to the identification of further key individuals in addition to those already interviewed. With more time it may have been useful to have interviewed other members of the personal policy network in addition to the original sample of key informants in order to verify the membership of the networks and the level of influence. This study made no attempt to

quantify the density or strength of relationships between individuals. Other studies have attempted to do so on the basis of the number of mentions by or contacts with others in the network. This would only be meaningful as a measure of influence if the sample was representative of the policy network or data was collected from all members of the network. Such attempts to quantify the influence of individuals within networks are interesting developments that deserve consideration in designing future studies of this sort.

11.3.5 Other questions and future research

Interest in and research on CAM is growing. Much of current research is designed to establish the efficacy of particular treatments using rigorous methods. Historically, a lack of research skills among CAM practitioners, identified as a problem by the House of Lords' Sub-Committee, has limited the amount of high quality primary research. Furthermore, many CAM practitioners were, and still are, sceptical of 'scientific' methods such as randomised control trials, believing that the holistic and individualised nature of many treatments and the therapeutic effect of the practitioners means CAM therapies cannot be appropriately tested using such methods. The Department of Health now provides financial support for the development of research capacity in CAM.

From a regulatory perspective, more systematic research specifically on safety issues is needed. The portrayal in the media of CAM practice is predominantly of a safe and natural approach to health. In fact, currently, there are few measures of risk. Adverse events are not systematically recorded, nor are incidences of misdiagnosis or missed diagnosis, omission of conventional treatment, or false claims. The claims that CAM practitioners pose indirect risks cannot therefore be systematically substantiated by evidence. While the evidence base on efficacy is growing, there is little interest in safety and quality research among CAM practitioners. Analysis of advertising claims (including the internet), complaints that are received by professional bodies, and legal cases (including those that settled out of court) would be useful data to understand the nature of the 'risks' faced by consumers of CAM services.

There is some research into the provision of CAM within the NHS but this is mostly descriptive. There would be value in health services researchers examining the design and quality of integrated services that already exist to inform future developments. There is some descriptive data on purchasing of CAM, but more research is needed to measure the cost-effectiveness of treatments to inform commissioners' decision-making. From a regulatory perspective it would be useful to understand to what extent lack of regulation is a barrier to integration and purchasing of CAM services. Examining whether other regulatory

strategies would be acceptable, or whether statutory professional self-regulation is necessary to provide adequate safeguards for providers and commissioners of health services, would also be useful.

There have been many surveys conducted to measure utilisation of CAM, each employing a slightly different definition of CAM (see chapter 2). It would be more useful if such information were regularly gathered in a standardised national population survey. Future General Household Surveys could usefully ask about visits to complementary therapists alongside questions on visits to GPs, specialists and hospital stays. Questions should be designed to overcome some of the methodological problems identified here. From a regulatory perspective, more in-depth research to determine whether patients are making informed choices is needed: for example, how did they find the practitioner, did they ask about qualifications, do they know about the registering bodies, where would they complain, etc. If patient 'self-responsibility' is to be encouraged we need to track whether information is actually reaching those using CAM services. High levels of public awareness are a prerequisite for voluntary regulation to be effective. It would also usefully inform an assessment of the need for further regulatory measures including mandatory disclosure.

Building on earlier research which collected data on the number of CAM practitioners, a more in-depth census to collect data on demographics of the workforce (e.g. gender, age, etc), training and qualifications, work setting, number of hours worked, and income and practice modalities is needed. Unless the target of regulation is understood it is unlikely to have the desired consequences. An inspection regime, such as that operated by the Healthcare Commission for private health care providers, would not be feasible if many practitioners operate from consulting rooms at home. If the majority of CAM practitioners practise more than one therapy then this would provide a robust justification for having a common regulatory framework rather than profession-specific standards as are currently being developed. Any future system of regulation is dependent on the ability of those who practise to afford the costs of regulation, whether this be registration fees to obtain a licence or the costs of accredited training courses. In this respect data on the average income of CAM practitioners would inform the development of regulation.

Finally, very little is known about the practice of CAM by statutorily regulated professionals. Detailed information on training in and practise of CAM by statutorily regulated professionals should be routinely collected either by employers (e.g. the NHS), regulators, or professional bodies. Research could be commissioned to gather these data.

The study has thrown up a number of broader issues that suggest empirical research beyond the policy domain of CAM. A number of these have already been mentioned in the

review of analytical approaches above. Firstly, this study has suggested an active role in policy-making by HRH the Prince of Wales. Is this unique or has he been active in other areas of public policy? Secondly, wider trends in regulation such as risk regulation and better regulation have had a significant influence on regulatory policy in this domain. Have these ideas infected other areas of health policy and what impact are they having? Thirdly, few alternatives to professional self-regulation were seriously considered. Are other models of regulation more acceptable in other occupational areas? Having reviewed the research findings, the analytical approach and the research design, in this final section of the conclusions I consider what the implications of the findings are for regulation of CAM practitioners and health care professional regulation in general.

11.4 How to regulate CAM practitioners?

The study was not normative: it did not set out to say whether or not there should be regulation of CAM practitioners, or if so how it should be organised. It sought to explain why regulatory policies took the form they did. In Chapter 3 I set out some of the different regulatory strategies available to policymakers and discussed examples of how these regulations applied to CAM practitioners in other countries. Through analysis of the regulatory process I have become aware of my own ideas about how CAM practitioners could be regulated. In this section I reflect back on the applicability of those strategies. In doing so I remain mindful of the peculiar nature of the CAM market (see Chapter 2).

Many of today's CAM therapists have more in common with the medical men (and women) of the 19th century than they do with modern health care professionals. Although the therapies studied here have professionalised, there remains disunity among practitioner groups. Beyond the 'Big 5' the picture is different again. Practitioner groups are even smaller and more highly fragmented. Though there is little hard data, it is generally thought that the majority of practitioners operate on a part-time basis, are self-employed and operate out of rented consulting rooms. There is, however, a great deal of diversity: therapists work in hotels, health clubs and beauty parlours, but also provide care in hospices and in GP surgeries. There are new therapies or "hybrids of existing therapies...appearing every day" (Jack, 2004, para 300). This makes it an extremely challenging environment in which to introduce effective regulation.

11.4.1 Command and control

Command and control regulation (or legislation) can be used to provide legal backing to occupational groups, giving them protection of title, restricting the use of certain

procedures or activities, making registration mandatory, or giving legal force to their disciplinary processes. These are the legal elements that distinguish self-regulation from enforced or statutory self-regulation and have been the main focus of policy discussions analysed in this study. The success of self-regulation (statutory or voluntary) is predicated on the existence of a single, unified, functioning professional body which can achieve consensus among the majority of practitioners about standards of entry to a register and the titles to be protected. As has been observed, the majority of CAM practitioners are not yet in this position. In the cases of acupuncture and herbal medicine the process of unification has required external impetus and resources to try and accelerate the process. Final agreement between the professional bodies, including traditional Chinese medical practitioners, is still being brokered before legislation can be introduced.

The use of reserved procedures legislation also requires that the technique or activity can be restricted to a clearly and legally defined group of people. The government are in the process of reforming Section 12(1) of the Medicine Act 1968, which applies to unlicensed herbal remedies made up to meet the needs of individual patients. The lack of any legal definition of a herbalist has in effect meant that anyone has been able to make up and supply an unlicensed herbal medicine under Section 12(1). The proposed reforms intend to address this legal uncertainty by restricting the supply of unlicensed herbal products to registered herbalists and other statutorily regulated professions. The regulation of herbal products is therefore dependent on the introduction of regulation of herbalists. Other CAM practitioners, such as naturopaths, homeopaths, and nutritional therapists, who currently dispense unlicensed herbal medicines as part of their practice will no longer be able to do so. This will increase the pressure on government to extend statutory regulation to other CAM practitioners. This policy is against the general direction observed in this study whereby the government is keen to reduce the legislative and regulatory burden.

A slightly different legal approach might afford greater opportunities for practitioners to become statutorily regulated without a significant legislative burden. It is similar to an approach adopted in Norway and Denmark and being considered in Ireland which combines statutory accreditation of professional associations with voluntary registration by individual practitioners. In Norway the law requires professional organisations who wish to seek 'approved' status to have professional standards and codes of practice in place, complaints procedures and sanctions, and guidance on compliance with data protection and informed consent. In addition, individuals who register must be legally recognised as self employed, an employee or partner in a firm, have the necessary liability insurance, and prove they are fit to practise. The law also sets out rules on marketing and information

disclosure. This legislative solution places the onus on professions to self-organize but puts in place minimal standards to ensure public protection. It is a model that the four UK health departments may wish to consider.

Alternatively a system of licensing similar to that for *Heilpraktiker* in Germany could be considered (see Chapter 3). The licensing examination in Germany tests basic knowledge of anatomy and public health, and ensures practitioners know the limits of competence and legal practice. Those wishing to specialise in a particular therapy have to meet certain additional requirements. This would assure minimum safety requirements while supporting multi-therapeutic practice.

11.4.2 *Self-regulation*

The current plethora of voluntary professional associations representing CAM practitioners is bewildering for the consumer (as it is for the reader!), and does not provide any guarantee of quality. A glance through the Yellow Pages shows the diversity of logos used by CAM practitioners affiliated to professional associations. Even chiropractors, who are statutorily regulated, advertise their membership of the British Chiropractic Association (BCA) or the McTimoney Chiropractic Association rather than giving their General Chiropractic Council (GCC) registration number - a much more important assurance of quality for the consumer. The proposals for a federal voluntary regulator aim to address this, though the details are still to be worked out (Jack, 2006).

Voluntary associations or guilds, in other sectors of the economy, use accreditation to provide an assurance of quality to consumers. Accredited providers can use the logo of the accrediting body in advertising and marketing. Consumer education reinforces this. In some cases, insurance or warranties may require work to be carried out by accredited providers. A well-known example of this is CORGI, founded in 1970 as the 'Confederation for the Registration of Gas Installers'. Gas installers were affiliated to CORGI on a voluntary basis until 1992 when it became a legal requirement for anyone installing or repairing gas fittings or appliances to be registered. CORGI (renamed the Council for Registered Gas Installers) was given the task by the Health and Safety Executive of maintaining a mandatory register of competent gas installers in the UK.

Drawing on the experience in other sectors, a successful system of accreditation might comprise the following:

- Passing an examination which tested basic knowledge e.g. of legal requirements, how to identify red flag events, and other core components common to any therapy;³⁶
- Providing evidence that the practitioner meets standards of practice and fitness to practise requirements, holds valid liability insurance, has no criminal record, etc.

Accreditation of CAM practitioners would enable private insurers and NHS purchasers to establish policies to fund only services provided by accredited practitioners. Contracting requirements and clinical governance rules might mean that any providers treating NHS-funded patients would only be able to employ or sub-contract accredited CAM practitioners. Referrals from GPs and other health care professionals might also be limited to accredited CAM practitioners. Public education would be needed so that consumers understood what accreditation meant, and what issues to consider when choosing a CAM practitioner. Consumer Direct, a government funded body, could usefully provide a fact-sheet on choosing a CAM practitioner similar to advice on choosing a solicitor. This information could be included in publications such as the Yellow Pages.

Certification, a similar model to accreditation but backed by the force of law, would ensure that only individuals who met the requirements of the regulator could legally use the title 'certified' or 'registered' with any CAM designation.

11.4.3 *Incentives*

The government, through its grant to the Foundation for Integrated Health, has in effect provided a positive subsidy to reduce the costs of professionalisation for CAM practitioners. Although the process is heavily dependent on the goodwill and time of the practitioners who have participated, it has enabled each of the therapies involved to benefit from the leadership of an independent chair. In addition, the government has given indirect financial support to acupuncture and herbal medicine by supporting the Regulatory Working Groups which met in 2002-2003, and since 2006 the working group which brings together acupuncturists, herbalists and traditional Chinese medical practitioners to prepare for statutory regulation. Given the slow pace with which voluntary self-regulation is developing even with these subsidies, it is perhaps worth considering how else incentives might be used.

³⁶ In the UK core competencies for complementary therapists have already been identified by Skills for Health.

Any new registering body must ensure the affordability of the fees. If practitioners are not willing to pay the fees they will continue to practise without registration, thus reducing the effectiveness of regulation in terms of public protection and standards. The institutional model that is needed to deliver robust professional self-regulation, even when shared between more than one profession, is expensive. If the full costs of establishing and operating the regulator fall to its registrants/members, as they do for other health care professionals, this is likely to result in high fees. Unlike health care professionals who are employed in the NHS, where fees are in effect taken out of salary, most CAM practitioners will have to make this a cost of doing business. These costs will either be passed to consumers in the form of higher prices, will result in more practitioners working full-time, or in fewer practitioners working. If one adds to these the costs that might be incurred by a practitioner if accredited training courses are longer and more expensive than those that are currently available, this model is likely to have a major impact on the market in CAM services. Government may have to consider subsidising the establishment costs of new regulatory bodies, or more radically have a single regulator with fewer of the profession-specific functions but a larger pool of potential registrants.

In addition to the costs of joining a professional association which are already tax deductible, the government could extend tax relief to course fees for accredited training courses and/or the costs of indemnity insurance. These would provide incentives to practitioners to participate in continuing professional development, and to ensure that they had sufficient insurance protection should any harm be caused to the patient.

11.4.4 *Market harnessing controls*

In the UK since April 2002, Primary Care Trusts (PCTs) have been fully responsible for commissioning health services for patients (though the introduction of practice-based commissioning is set to change this again). Through the specification of contracts PCTs could require providers of CAM services to comply with certain standards or specifications. For example, they could include a requirement that all contracted practitioners have liability insurance. In future it is more likely that PCTs will hold contracts with large third-party providers, who might as part of their services offer access to CAM practitioners. It would therefore be for the third party provider to ensure that the standards they required of the CAM practitioners were sufficient to satisfy the terms of their contract with the PCT.

The provision of CAM services by conventional health care professionals could also be regulated through contractual agreements (either directly with employers or in nationally negotiated contracts). Employment contracts could specify the requirements that would

need to be met in order for professionals to practise CAM (e.g. training standards), and set out rules governing the circumstances in which CAM can be offered (e.g. palliative cancer care).

The premises from where CAM practitioners conduct their business could also be subject to regulation and licensure. In England independent health care providers are required to register with the Healthcare Commission. However, currently this regulation only applies to private acute and mental health hospitals, clinics where services are provided by medical practitioners, and establishments which provide any services from a list of treatments.³⁷ Registration, inspection and accreditation of facilities could be required of clinics where CAM practitioners operate. However, as many CAM practitioners work in single-handed practices, treat clients in their homes or at their place of work, or rent consulting rooms, such a system is likely to be unworkable in practice.

11.4.5 *Disclosure*

Most CAM practitioners in the UK currently operate subject to a number of general trading provisions as well as a voluntary advertising code which contains specific rules governing health claims. The monitoring and enforcement of compliance with these marketing requirements is currently weak and relies largely on complaints being lodged. If enforcement were to be stepped up trading standards officers, who are currently responsible for enforcement of these provisions, may require additional training or, given the scale of the task, dedicated officers might need to be recruited. Stricter rules governing the claims that practitioners can make and further professional guidance on advertising could be introduced, backed up by disciplinary procedures or legal penalties for failure to comply. Disclosure requirements could be extended for CAM practitioners to include valid certificate of insurance and proof of training and qualifications.

It is not easy to envisage how literature distributed to patients in a clinic or claims made in adverts posted on websites could be monitored, other than by promoting greater awareness among practitioners and among consumers about the standards and how to make a complaint. The guidance published for Chinese medical practitioners by the Trading Standards Institute makes clear the requirements of existing legislation and could be replicated for all CAM practitioners (Trading Standards Institute, 2006). In addition, education about these legal provisions and how they apply to CAM practitioners could be a

³⁷ Providers who supply medical treatment under anaesthesia or sedation; dental treatment under general anaesthesia; obstetric service and in connection with childbirth, medical services termination of pregnancies; cosmetic surgery; treatment using prescribed techniques and technologies e.g. laser and intense pulse light therapy, hyperbaric oxygen chambers, private dialysis, IVF and endoscopy; or treatment or nursing (or both) for persons liable to be detained under the Mental Health Act 1983 must register.

compulsory component of all accredited training courses, or knowledge of the law and its application to CAM practitioners could be made a condition of accreditation or licensing.

The Kerr-Haslam report suggested that statutorily regulated professionals working within the NHS should get written prior approval from their 'team' to use new or unorthodox treatments. This level of disclosure is something that most employers would require in order to satisfy their clinical governance requirements, but it is not clear whether these recommendations have been implemented. However, disclosure alone does not provide any assurance to employers or patients that these professionals are adequately trained to provide that particular therapy. In the UK, although there are training courses for doctors, nurses, etc., these courses are not accredited and there are no requirements to prove competency in order to practise. In Germany, on the other hand, there are recognised specialist qualifications in CAM for doctors, with regulations defining the standards required. Doctors are allowed to use protected titles if they have the appropriate specialist qualification. Specialist CAM qualifications for statutorily regulated health professionals would ensure levels of competence and might allow access to protected titles without having to meet the full requirements required of non-medical CAM practitioners. This would alleviate the concerns of the large numbers of doctors, nurses and other healthcare professionals who use acupuncture that the current proposals for the statutory regulation of acupuncturists do not directly address their circumstances.

11.4.6 *Rights and liabilities*

Patients already have the ability to sue a CAM practitioner for negligence. The problem with reliance on such a system is that it does not prevent the harm from occurring, it requires the plaintiff to have access to legal (and financial) resources to pursue the case, there must be sufficient evidence to prove negligence, and finally the defendant, if found guilty, must have sufficient assets to meet the compensation award. Some of these issues are no different to the limitations of medical negligence. However, many CAM practitioners in the UK do not have personal liability insurance. They are self-employed and practise from home or out of rented consulting rooms, and are unlikely to have assets to cover the legal costs or compensation awarded. To address this personal liability insurance could be mandatory for practising CAM practitioners (Stone, 2000, p287). An additional problem is the ability to define what constitutes negligent practice. The Bolam test is usually applied, which expects a professional to meet standards that are in line with a responsible body of opinion. In most CAM therapies there is no single statutory body which sets out standards of practise. In fact the body of knowledge that defines the therapy is often highly contested, making the test more difficult to apply.

11.4.7 *Public compensation*

Given the difficulties of obtaining compensation through the courts, an alternative would be to set up a complaints scheme with an Ombudsperson which would give patients the right to redress for harm caused by CAM practitioners (Bloomfield, 1997, para 58). Patients would give up the right to sue the CAM practitioner in return for financial compensation.

In summary, there are many possibilities as to how regulatory tools could be used in the UK to ensure the safety of patients, promote a more effective market in CAM services, and raise the standards of training and practice by CAM practitioners. These ideas have emerged as a result of the research process, and I believe are worthy of further research and discussion.

11.5 The future of professional self-regulation

There have been many changes and reforms to the systems of statutory regulation of health care professionals, but none has sought to radically alter the fundamental form of the original medical model of professional self-regulation. The main functions remain: to set educational standards for entry to a register, and to remove registrants who are deemed unfit to practise. Since the Health Act 1999 changes to statutory professional regulation can be made by an Order in Council rather than primary legislation (Allsop, Jones et al., 2004).

The future of professional regulation is currently under debate. After the publication of the Shipman Inquiry Fifth Report Sir Liam Donaldson, the Chief Medical Officer (CMO), was asked by Ministers to review arrangements for protecting patients from harm caused by the poor performance of doctors (Chief Medical Officer of England, 2006). The Department of Health also established an internal review led by Andrew Foster, former Director of Workforce at the Department of Health, to look at non-medical professional regulation (Department of Health, 2006c). It examined how new and extended professional roles should be regulated and what changes are needed in the structure, functions and number of healthcare regulators. A government consultation on the recommendations of the two reports closed in November 2006 and the response is awaited.

The Donaldson Report and Foster Review make numerous recommendations concerning the organisation of professional self-regulation, too many to summarise here. Although there was no mention of complementary therapists or the practice of CAM by doctors in the reports, they indicate the direction of regulatory policy. I briefly discuss the implications

of the recommendations of these two reports for the regulation of CAM practitioners in future.

Firstly, the reports see regulation as necessary to ensure that the practice of health care professionals is safe and meets acceptable standards. In this sense professional regulation is intended to reduce risk. The CMO commissioned research on regulatory frameworks used in other high-risk industries such as nuclear power, off-shore oil and civil aviation, and concluded that “Regulation in these industries may be expensive but the fruits, in terms of quality and safety, far outweigh this cost” (Chief Medical Officer of England, 2006, p*x*). The term ‘risk-based regulation’ is also used, meaning that regulatory efforts should be focused where “risks are higher or a supervisory framework is lacking”. Unless CAM therapies are assessed as posing a significant risk to patients they are unlikely to be statutorily regulated. This fits with wider government policy on risk and regulation (Better Regulation Commission, 2006). Regulation is no longer about regulating all possible risks but rather about regulation being proportionate to risk.

Secondly, both reports talk about ‘light-touch regulation’ and emphasise the importance of the principles of better regulation. However, the CMO concludes that because of the risks of medicine and the historical context of regulatory failures regulation “cannot be left solely to professionalism, market forces or luck” (Chief Medical Officer of England, 2006, p167). He therefore makes the case for further reform of the GMC and for strengthening regulation. The requirement on government departments to ensure that regulation is cost-effective and to consider alternative strategies to legislation might, however, result in different strategies and institutional forms being proposed. Finding an appropriate balance between the costs of regulation and acceptable levels of risks will be a challenge for all regulatory policies going forward, including those related to CAM practitioners.

Thirdly, the reports affirm the need for greater public accountability. The CMO commissioned research on approaches to medical regulation in other countries (Allsop and Jones, 2005). He concluded that although there is no ‘blueprint’ the general trend is that “regulatory bodies are becoming more accountable, lay involvement is much increased and adjudication is often an independent function” (Chief Medical Officer of England, 2006, p*x*). There appears to be a growing consensus on these issues in the UK. Both reports recognised that the election of professional members to the councils supported the public perception that the councils act in the interests of the profession. They recommended that either all (Donaldson) or some (Foster) of the professional members should be appointed by a body such as the Public Appointments Commission. Foster invited comments on whether the councils should have lay or professional majorities (the eight regulators of

non-medical professionals currently have small, varying professional majorities) (King's Fund, 2007 forthcoming). Any future proposals for the regulation of CAM practitioners will need to demonstrate that the regulatory bodies are accountable to the public.

Fourthly, both reports recommended that the complaints process be simplified and disciplinary proceedings made more independent. These are broadly in line with the Shipman Inquiry Fifth Report, which recommended that adjudication should be made independent of the profession. It envisaged that the profession would still receive, process and investigate complaints and decide *prima facie* whether there is a case to answer, but that the adjudication would be by an independent panel (Department of Health, 2004b). Both reports agreed that it should be clearer and easier for complaints to be lodged. Foster proposed that there be a single portal through which all complaints can be made, irrespective of who ultimately deals with them. Both voluntary and statutory bodies with responsibilities for enforcing standards of practice of CAM practitioners will need to ensure that their disciplinary procedures are both fair and independent. A single complaints portal has been suggested for CAM practitioners by consumer organisations, and would help to ensure that complaints were dealt with fairly.

The Donaldson report recommends that more regulatory responsibilities be devolved to a local level including the ability to deal with the initial investigation stage of any complaint. Only serious cases would be referred up to the central council. It is not clear how devolution can apply to professionals (such as CAM therapists, physiotherapist, dentists and pharmacists) who work independently in private practice or as independent contractors however. Consequently it is not envisaged that there will be local mechanisms for dealing with complaints concerning CAM practitioners.

Fifthly, the reports both recommend that requirements for revalidation be introduced or strengthened. Foster proposed that revalidation for non-medical healthcare professionals be based on the Knowledge Skills Framework introduced as part of Agenda for Change. In Donaldson's report revalidation would rely in part on the NHS appraisal procedures, but in addition doctors would have to be re-certified for inclusion on the GP and specialist registers against standards set by the relevant Royal Colleges or specialist associations. Following earlier criticisms of the GMC's proposals for revalidation, Donaldson emphasised that the appraisal should be summative (involving judgement against criteria and the possibility of failure) and not solely formative (educational) (King's Fund, 2007 forthcoming). Reliance on the NHS as both a source of data to monitor performance and to provide a mechanism for revalidation does not fit with the policy to increase the plurality of providers in the NHS, at least in England. The Donaldson Report did recognize

that doctors who work on short term contracts or under locum arrangements provide “special challenges for regulation” (Chief Medical Officer of England, 2006). The system will have to rely on disclosure by locum agencies and those employing fly-by-night surgeons to the GMC. The extent of agency work in nursing and among many other health care professionals is not likely to diminish, and new models of provision will make reliance on employers more rather than less challenging. Where practitioners are self-employed, as the majority of CAM practitioners are, these arrangements will not be workable. For these practitioners these responsibilities will still primarily fall to the regulators. CAM regulators will need to demonstrate that the mechanisms for revalidation are both summative and formative. It is unlikely that achievement of a minimum number of continuing professional development credits will be sufficient in future.

One issue that the reports were expected to address was the number of regulators. The Donaldson Report was silent on this issue. The Foster Review identified a number of benefits of consolidation, but in the end ruled out reducing the number of existing regulators on “practical grounds” (Department of Health, 2006c). There are of course strong institutional and professional interests in maintaining the status quo. The report recommended the issue be reviewed in 2011. It was hoped that “collaboration and harmonisation” between regulators might preclude the need for structural changes. New health care professions will be required to join an existing council, and over time more common structures will be developed under the auspices of the CHRE. It is therefore unclear where this leaves the proposals for a CAM Council. It seems unlikely that the government will wish to create another regulator. It is possible that earlier proposals that CAM practitioners join the Health Professions Council (HPC) might be resurrected for acupuncturists and herbalists, even though proposals for a new CAM Council have already been consulted on. The emphasis on collaboration suggests that the government will continue to support the establishment of a federal structure for voluntary regulation of CAM practitioners.

In addition to these observations about how wider approaches to health care professional regulation might affect CAM practitioners, the findings of this study provide some useful insights into the likely direction that reforms to the regulation of health care professionals might take.

First, it is unlikely that we will see a radical shift away from the current model of regulation, i.e. professional self-regulation sanctioned by the state. Within the health sector there remains a strong commitment to self-regulation. Other regulatory strategies were largely not considered. This study has shown that occupational groups will defend their right to

self-determination. Professional regulation is seen as vital to professional identity as is having one's own register and governing council. Regulation is the battleground where jurisdictional claims are won and lost. Demarcations between professional groups and sub-specialties are likely to be fiercely defended. It will therefore remain a controversial political arena with strong resistance to reform, despite the changing reality of work roles.

Second, the number of regulators is likely to reduce rather than increase. Although professionals will want to keep their own single regulatory body, there will be increasing pressure for existing regulators to take on new professions and *in extremis* to merge. The proposals for a CAM Council reflected the government's wish not to see a proliferation of professional regulators. It was designed so that other CAM practitioner groups could be added in the future. As highlighted above, this will bring the state into conflict with professional groups.

Third, government will favour self-regulation over external regulation and seek to minimise the introduction of new regulations. After a period of growth in regulation, which created the 'audit society' or regulatory state, there is now an emphasis on responsive or light-touch regulation and a desire to reduce the burden of regulation on both businesses and the public sector. This study found that the state is actively supporting self-regulation, and preferring to invest in the development of voluntary regulation rather than introduce statutory regulation for CAM practitioners. It is unlikely that external regulation will be introduced to control the practice of individual health care professionals at a time when the government is trying to reduce the size of the Department of Health, the number and size of independent regulators and arms-length bodies (Department of Health, 2006b) and place limits on spending on non-clinical services.

Fourth, entry to a register and maintenance of registration (or licence to practise) will depend on meeting explicit measurable standards. Although much of the debate in CAM was about 'grandparenting' and entry to a new register, some of the issues are common to registration and revalidation of existing health care professionals. CAM practitioners registered by the proposed CAM Council will have to demonstrate that they are fit to practise: in good mental and physical health, no criminal record and no child protection issues. They must also demonstrate competence obtained through specific training. They will also be expected to have liability insurance and language competence for initial entry to the register. It is likely in future that there will be a standard set of requirements that all health care professionals will have to meet in order to register and be re-licensed. In CAM, requirements for re-certification have been set by and implemented by the regulator.

Fifth, regulators will have to become more overtly accountable to the public. The inclusion of a statutory duty to promote the profession in the constitutions of both the GOsC and the GCC caused confusion about the respective roles of regulatory and professional bodies. In order to ensure the public interest is sufficiently reflected by regulatory bodies a number of measures, highlighted in proposals for CAM practitioner regulation, are likely to be applied to other health care professional regulators. These include establishing direct accountability to parliament (as opposed to Privy Council), publishing annual reports and audited accounts, increasing lay representation on councils and committees (to form half of the membership or a slight majority), appointing all professional members (replacing members who were previously elected), and appointing a lay chair. Although there is little evidence that lay representation is more effective, such reforms are likely to win greater public support and may re-establish the legitimacy of regulatory structures. There will also need to be a clear separation of professional representative functions, so professional associations will continue to have an important role in this respect.

Sixth, new professional roles will have to unify and organise themselves in order to be taken seriously as 'aspirant' professions. Foster recommended that "Any new profession coming into statutory regulation should be regulated by one of the existing regulatory bodies, most likely the HPC" (Department of Health, 2006c, p42). The Foster report talks about setting criteria that new professions will have to meet. These would apply across all regulators, not just to the HPC. In the early period of this analysis the state expected CAM practitioners to 'get their house in order'. Osteopathy and chiropractic did so successfully, but the state had to actively invest in the development of acupuncture and herbal medicine. No CAM practitioners were able to meet the criteria set by the HPC. The problem with this approach is that it relies on the professional group to organise itself. If there are risks associated with the practice the public are unlikely to find it acceptable that these practitioners remain unregulated, and the government may have to invest in their development. Although currently many of the people recruited into these new roles (such as anaesthesia practitioner, emergency care practitioner, endoscopy practitioner, medical care practitioner and surgical care practitioner) are from existing statutorily regulated professions, in future this may not be the case.

Seventh, new and innovative forms of regulation are needed to deal with practitioners whose activities cross existing professional boundaries, such as those taking on extended roles. The regulation of extended roles has much in common with the debates about how to regulate the practice of CAM by statutorily regulated professionals. For example, a medical acupuncturist is currently not required to meet any defined standards in order to

practise acupuncture, although this may be his or her main professional activity. The government rejected the idea proposed by the Acupuncture Regulatory Working Group (ARWG) that there should be a second tier of registration for medical acupuncturists already regulated by the GMC or another statutory regulator. It indicated that dual registration was neither desirable nor necessary. Interestingly, the Foster report introduces the idea of ‘distributed regulation’, but it remains unclear how the distribution of regulatory functions would work in practice. For example, would practitioners have to meet the revalidation requirements of both regulators in order to use the protected titles? Having a mechanism for setting standards of training and practice in order to practise a specialist interest or perform an extended role (beyond those that are established by existing Royal Colleges) may be necessary to protect the public from poor standards of care, and would better enable providers to meet clinical governance requirements.

It would be premature to sound the death knoll on professional self-regulation. The survival of institutions depends in part on their ability to adapt to changing circumstances. The GMC, despite controversy at its establishment and serious questions about its competence since, has reformed and survived. But the regulatory challenges are mounting, and further incremental changes to the medical model of professional self-regulation may not be sufficient.

There is a dearth of ideas about alternative regulatory approaches. The majority of recommendations in the Foster Review and the Donaldson Report proposed minor changes to self-regulation, the distribution of regulatory functions, and the institutional arrangements for regulatory bodies. Other than a brief mention of financial incentives associated with premiums charged by insurers providing liability cover, other regulatory mechanisms were not considered. Existing institutional structures act as powerful conservative forces, and appear to have constrained the flourishing of alternative ideas. Despite commitment to the principles of better regulation, the use of regulatory impact assessment across government, and an emphasis on light-touch or responsive regulation, the dominant idea is that regulation be carried out by professionally-led bodies.

It is doubtful in the present climate whether a new CAM Council will be created. Even if it is, the process for including other therapists will be slow and cumbersome. It will require practitioner groups within each therapy to unify and establish a consensus about standards of education and practice. The proliferation of new CAM therapies means that if regulation is to reach beyond the practitioners of osteopathy, chiropractic, acupuncture and herbal medicine it will have to take a radically different form. The answer may lie in a fuller exploration of alternatives to professional self-regulation such as disclosure and trading

standards. While use by the public continues to grow, and the number of practitioners and training courses burgeons, there will be pressure on government to act. Reconciling the government's duty to protect the public with its desire to reduce the regulatory burden and maintain consumer choice will be challenging.

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Appendix 1. Glossary of therapies

Acupuncture

Originating from China, acupuncture involves inserting small needles into various points in the body to stimulate nerve impulses. Traditional Chinese acupuncture is based on the idea of 'qi' (vital energy) which is said to travel around the body along 'meridians' which acupuncture points affect. Western acupuncture uses the same needling techniques but is based on affecting nerve impulses and central nervous system. Acupuncture is used in the West as an anaesthetic-agent and also as an analgesic (House of Lords Select Committee on Science and Technology, 2000a). The definition of acupuncture produced by the National Institutes of Health (NIH) for inclusion in Medline reflects some of the variations in practice: "Treatment of disease by inserting needles along specific pathways or meridians. The placement varies with the disease being treated. It is sometimes used in conjunction with heat, moxibustion, acupressure, or electric stimulation" (National Institutes of Health, 2006).

Chiropractic

In the modern British context chiropractic is used almost entirely to treat musculo-skeletal complaints through adjusting muscles, tendons and joints and using manipulation and massage techniques. Diagnostic procedures include case histories, conventional clinical examinations and x-rays (House of Lords Select Committee on Science and Technology, 2000a). Originally it was based on the idea that 'reduced nerve flow' led to disease. The NIH definition perhaps reflects the situation in the US where chiropractors as a profession are more widely recognised: "Spinal adjustments made by a chiropractor to relieve pressures on the spinal cord for improvement of health" (National Institutes of Health, 2006).

Herbal medicine

Herbal medicine or phytotherapy is a system of medicine which uses various remedies derived from plants and plant extracts to treat disorders and maintain good health (House of Lords Select Committee on Science and Technology, 2000a). It relies on the principles of pharmacology. A survey of UK herbal practitioners, who represent only a small proportion of herbal use in the UK, indicated that the most frequently treated conditions were premenstrual syndrome, irritable bowel syndrome, eczema and arthritis (Barnes, 1998). There is widespread use of herbal medicine among naturopaths and those who practice nutritional medicine and a large over-the counter market.

Homeopathy (also homoeopathy)

Homeopathic medicines are produced through a process of serial dilution and vigorous shaking ("potentiation"). The dilutions are repeated so many times that there is less than one molecule per dose and it is suggested that benefit is from the energetic life force of the original substance (National Institutes of Health, 2006). Homeopaths believe that the dilutant retains a memory of the original substance ("the memory of water") (Ernst and Dixon, 2004). Homeopathic remedies use highly diluted substances that if given in higher doses to a healthy person would produce the symptoms that the dilutions are being given to treat. When assessing the patient homeopaths often take into account a range of physical, emotional and life style factors which contribute to the diagnosis (House of Lords Select Committee on Science and Technology, 2000). Homeopathy is employed mainly for mental, infectious and rheumatological disorders (Colin, 2000). According to a survey of professional organisations the four most important medical indications are respiratory problems, menstrual complaints/pre-menstrual syndrome, arthritis/rheumatic conditions and irritable bowel syndrome (Long, Huntley et al., 2001).

Osteopathy

Osteopathy is a system of diagnosis and treatment, usually by manipulation, that mainly focuses on musculo-skeletal problems. A few schools claim benefits across a wider spectrum of disorders. Historically it differs from chiropractic in its underlying theory that it is impairment of blood supply and not nerve supply that leads to problems. However in practice there is less difference than might be assumed. Mainstream osteopathy focuses on musculo-skeletal problems; but prior to osteopathy gaining statutory protection of title, other branches of this therapy purported to diagnose and treat a range of disorders. One such branch is known as cranio-sacral therapy (House of Lords Select Committee on Science and Technology, 2000).

Appendix 2. List of documents included in the documentary analysis

Submissions to Department of Health consultation (18)	
BAAB DH Consultation response	FIH DH consult response full text
BACc DH consultation response	GDC DH consultation response
BHA FacHom DH consultation response	GOsC DH consultation response 070604
BMAS DH consultation response	NPSA DH consultation response
CA DH consultation response jun04	RC Midwives DH Consultation response
CHRP DH consultation response	RC Ophthalmologists DH consultation
CORH DH consultation response	RCGP DH consultation response
EHPA DH consultation response June 0	RPSGB DH consultation response
EHPA MHRA consultation response MLX	SocHom DH consultation response 0504
Emails (7)	
FIH Regulation Update 0104	FIH Regulation Update 0504
FIH Regulation Update 0204	FIH Regulation Update 0604
FIH Regulation Update 0304	KF Graham Hart email
FIH Regulation Update 0404	
Parliamentary debate and reports (12)	
HoC Chiropractors bill 1st Reading	HoC Osteopaths bill 3rd Reading
HoC Chiropractors bill 2nd Reading	HoC Parliamentary Qs 180406
HoC Chiropractors bill 3rd Reading	HoC Tredinick 240196
HoC GOsC Written Answer 110500	HoC Tredinick various
HoC Osteopaths bill 1st Reading	HoL Debate on CAM report 290301
HoC Osteopaths bill 2nd Reading	Lord Walton HoL debate on CAM
Oral and written evidence to House of Lords Science and Technology Committee (87) ‡	
AACP HoL written	GCC HoL written supp
AcadMedSci HoL oral	GDC HoL oral
AcadMedSci HoL written	GMC HoL oral
Ayurvedic MA HoL written	GMC HoL written
BACc HoL oral	GOsC HoL oral
BACc HoL written	GOsC HoL written
Baum HoL written	GOsC HoL written supp
BAWA HoL written	Healthwatch HoL oral
BCA HoL written	Healthwatch HoL written
BCMA HoL oral	Healthwork HoL oral
BCMA HoL written	Healthwork UK HoL written
BDA HoL oral	Hom MA HoL written

BDA HoL written	ICM HoL written
BMA HoL oral	Integrated Med Gp HoL written
BMA HoL written	Lewith HoL written
BMAS HoL oral	NHS Alliance oral evidence HoL
BMAS HoL written	NHS Alliance written evidence
Brit Coll Nat Osteo HoL written	NHS Confed HoL written
Brit Sch Osteo HoL written	NICE HoL oral
Budd HoL written	NIMH Denham HoL written
CA HoL oral	PA HoL oral
CA HoL written	Parl Gp CAM HoL written
CHI HoL oral	Patient Concern HoL written
CHM&HCLtd HoL written	POPAN HoL written
CMAssoc Suppliers HoL written	RC Anaesthetists HoL written
Coll Chiro HoL written	RCCM HoL oral
Consumers for Health Choice HoL writ	RCGP HoL oral
CPSM HoL written	RCGP HoL written
DH HoL oral I	RCHM HoL written
DH HoL oral II	RCN HoL oral
DH HoL written	RCN HoL written
Eastern Med Tibb Pract Assoc HoL wri	RCOG HoL written
EHPA HoL oral	RCP Edin HoL written
EHPA HoL written	RCP HoL written
Ernst HoL written	RCPaed and Child Health HoL written
FacHom, Hom Trust, BHA HoL oral	Royal Colleges HoL oral
FacHom, Hom Trust, BHA HoL written	Royal London Hom Hosp HoL written
FIH HoL oral	Soc Hom HoL oral
FIH HoL written	Soc Hom HoL written
FIH HoL written supp	Stone HoL written
FTCM HoL written	Tibb NMF HoL written
GCC HoL oral	Tredinnick HoL written
GCC HoL written	UKCC HoL oral
	UKCC HoL written
Interviews (22)	
Becky Sldwell interview	Michael Dixon telephone
Frances Blunden Interview	Michael Fox Interiew
Gordon Brown interview	Michael McIntyre Interview
Graeme Catto Interview	Michael O'Farrell Interview
Jonathan Coe Interview	Michael Pittilo Interview
Julie Stone Interview	Mike Cummings interview
KF Niall Dickson interview	Nigel Clarke Interview
Lord Chan Interview	Pamela Jack Interview

Lord Walton Interview	Richard Woodfield Interview
Maggy Wallace Interview	Robert Maxwell Interview
Michael Dixon interview	Stephen Gordon interview
Articles and letters in the published media and journals by individuals (36)	
Baum letter to POW BMJ 100704	Guardian Dixon letter 240805
BBC Case notes Homeopathy	Independent FIH bk Ernst 60205
BBC R4 Other Medicine 1	Observer Ernst savages homeo 181205
BBC R4 Other Medicine 2	Osteo article Standen 1993
BBC R4 Other Medicine 3	POW Daily Mail integrated 200502
BBC R4 Other Medicine 4	POW Guardian comp 280204
BBC Row over Smallwood 240805	POW NHS Mag Integrated 050100
BMA press release 011199	POW PR Smallwood report 1005
BMJ News on DH acu and herb prop	POW Telegraph homeo 211097
CHRP Stone CM regulation BMJ 1996	POW Telegraph integrated 180403
Ernst BMJ Herb Med 181003	POW Times comp 301200
FIH Fox BMJ letter 091004	Stone BMJ article BMJ author replies
FIH PR consultation on fed structure	Telegraph FIH pat guide 091004
FIH PR DH grant 2005	Telegraph POW comments on CM 131005
Guardian Ernst Integral risk 160805	The Times Bueno 100200
Guardian Horton letter 081005	The Times POW cost letters 290805
Guardian POW cost review CAM 240805	The Times POW cost study 240805
Guardian POW cost study 61005	Times letter docs vs CAM 230506
Memos (31)	
Acupuncture documents	FIH documents
Analysis	FIH Trustees
Australia herbal recall	HoL Committee Members
BMA documents	HoL List of Witnesses
CA documents	Homeopathy documents
Chiropractic documents	International literature
CHRP Documents	Interviewee biographies
Consumer herbal interest groups	Julie Stone documents
Contacts	KF documents
DH consultation responses	MHRA documents
DH documents	POW affiliations
Documents suggested by interviewees	Questions for RK
EHPA documents	Regulating TCM in Singapore
EU Herbal Directive	REMINDER OF PROGRESS
Evidence systematic reviews	Themes and preoccupations
	US NAS report on CAM 2005
Published documents (35)	
ACHCEW Briefing on CAM	FIH consultation on fed structure

Acupuncture RWG	FIH federal consultation 2006
BMA book 1986	FIH Guide for patients 2005 extract
BMAS Annual Report 2004	FIH Reg Prof Info App Apr 05
CA article on CAM regulation	FIH Setting the agenda for the futur
CA prof reg 21st C 1998	FIH student guide extract 2005
CA Which guide to CT	GMC Developing Risk-based Regulation
CORH Accreditation Proposals	GMCdeveloping_medical_regulation_200
CORH Codes of ethics and practice No	Herbal Medicine RWG
CORH consultation doc	HoL 6th Report on CAM 211100
DH consult on acup and herb 2004	KF Annual Review 2003-04
DH consult on acup and herb response	KF Chiro Working Party†
DH response to HoL report 2001	KF Osteo Working Party†
EU Directive Trad Herb Med Apr 04	MHRA Consultation document MLX299
Exeter DH 2nd report 2000	NCC prof reg health care
Exeter DH Info Pack 2000	POW Smallwood Report CAM NHS 1005
FIH A Way Forward 1997	Wallace WHO Guide
FIH Article from NT	
Speeches (29)	
BAAC Farrell VSR seminar 0905	POW BMA install 070782
BACc Bishop FIH KF conf Apr 04	POW BMA Millennium 061100
BMAS Cummings FIH KF conf Apr 04	POW FIH Cancer 240604
CHRP Stone FIH KF conf Apr 04	POW FIH Integrated 111203
CHRP Stone VSR seminar 0905	POW FIH Integrated 140599
CORH Gordon FIH KF conf Apr 04	POW FIH Regulation 191102
DH Sidwell FIH KF conf Apr 04	POW FIH strategy 220503
DH Sidwell FIH seminar 2003	POW Integrated 280598
FIH Jack VSR Seminar 0905	POW Integrated Writers 160999
FIH VSR Seminar panel 0905	POW KF Integrated 211097
MHRA Woodfield FIH KF conf Apr 2004	POW KF President 150600
NIMH Denham FIH KF conf Apr 4	POW WHA 230506
POPAN Coe FIH KF conf Apr 04	RCPsych HoL written
POPAN Coe FIH KF conf full text Apr	Reg CHM Lampert FIH KF conf Apr 04
POW BMA CAM 141282	
Web (13)	
C4HC appeal letter	ICM background
Dr Foster Ethics Cttee 010604	ICM proposals for single Act 2001
Dr Foster website 030205	ICM response to HoL 2001
EHPA briefing SSR Herbalists 2001	POPAN website comp ther 030205
EHPA circular SSR Herbalists 1999	POW web on FIH 080205
Healthwatch web	POW website health work 1205
HFM appeal letter	

Appendix 3. List of interviewees and dates

Gordon Brown, civil servant, Department of Health, 17th August 2004 at Skipton House, Department of Health, London.

Frances Blunden, Principal Policy Adviser, Which? 8th October 2004 Consumers Association, London

Graeme Catto, President of the GMC, 1st March 2005 at King's College, London.

Lord Chan of Oxton, House of Lords, 16th March 2005 at private office, Milbank, Westminster.

Nigel Clarke, General Osteopathic Council, 14th March 2005 at GOsC, London.

Jonathan Coe, Chief Executive, POPAN, 12th April 2005 at POPAN, London.

Mike Cummings, Medical Director, BMAS, 3rd March 2005 at LSE

Michael Dixon, Chief Executive, NHS Alliance

Telephone interview 15th February 2005

Face to face 15th March 2005, at the Liberal Club †

Michael Fox, Chief Executive, Foundation for Integrated Health, 19th October 2004 at the Foundation for Integrated Health, Holloway, London

Pamela Jack, Regulation Programme Manager, Foundation for Integrated Health, 21st September 2004 at the Foundation for Integrated Health, London.

Robert Maxwell, telephone interview, 13th May 2005

Michael McIntyre, Chairman, EHPA, Wednesday 27th October 2004 at the King's Fund, London.†

Mike O'Farrell, Chief Executive, British Acupuncture Council, 28th September 2004 at the British Acupuncture Council, London

Michael Pittilo, Vice Chancellor, University of Hertfordshire, 29th September 2004 at the University of Hertfordshire, Hatfield

Becky Sidwell, civil servant, Department of Health, 1st March 2005 at the LSE, London.

Julie Stone, Deputy Director, Council for Healthcare Regulatory Excellence, 22nd March 2005 at CHRE, London.

Maggy Wallace, Chair Council for Organisations Registering Homeopaths, 14th October 2004 at the LSE, London

Lord Walton of Detchant, House of Lords, 24th February 2005 at the House of Lords.

Richard Woodfield, European Policy Manager, MHRA, 15th December 2004 at the
MHRA, London.

Appendix 4. Sample interview schedule

Why does the level of state intervention in the regulation of CAM practitioners differ between activities in the UK? For example why are some practitioners statutorily regulated, why are some encouraged (by the state) to establish voluntary professional regulation and others are free to establish voluntary associations?

What factors have resulted in the different policy responses? What has been the role of different stakeholders in the policy community in influencing these responses?

Why does the model of professional self-regulation dominate policy ideas?

Why regulate? What persuasive arguments are there for regulating CAM practice?
Why regulate some therapies and not others?
Why the medical model of regulation?
Has there been a change in policy? If so why?
What has been your strategy? Who are your allies and who are your enemies?

Prelims

Clarify the nature of the research and the purpose that the interview data will serve.
Clarify whether the interview will be anonymous or assigned.
Ascertain time available for the interview and the format of the questions (e.g. semi structured).
Establish whether the individual gives consent for the interview to be recorded.
Any questions?

Introductions

Name, position in the organisation
What was your role in the HRWG? How long did you hold the position?
Why did you take on the role?
Had you been involved with or had an interest in CAM previously?

Reasons/Justification

Why regulate CAM practice/herbal medicine? What in your view are the most persuasive arguments for regulating CAM practice?
Why do you think regulation is needed? What is the purpose of regulation? Is that true for all CAM therapies? Why regulate some therapies and not others?
[If mention 'protect public' or some such phrase then probe]
What do you understand by public harm? What risks do you think the public should be protected against?

Types of regulation

What sort of regulation would be the most appropriate? Why?
What are the weaknesses of voluntary self-regulation?
What are the perceived benefits/weaknesses of statutory regulation?
What do you perceive as the benefits /outcomes of regulation to be? What are the costs or potential disbenefits? Who is most affected by the policy?
Structure and organisation
How should regulation operate?

What do you think of DH proposals to establish a single statutory CAM council for the regulation of all practitioners? What is your view of the ARWG proposals to establish separate Councils?

Do you think regulation should be different for those with a recognised health qualification practising CAM such as doctors, nurses and physiotherapists and those without?

Who should regulate? What is the role of professionals, lay members, etc.
What should the regulators do? What functions should they perform?

Why the medical model?

How influential was the approach taken by osteopaths and chiropractors in establishing a single professional council?

Why do you think this model of regulation has been adopted?

Were other approaches considered?

Was any consideration given to how other country's regulate TCM practitioners?

Policy process

What have been the main drivers for establishing statutory regulation for herbalists?

What was your role and that of the HRWG in the development of professional regulation for herbalists?

Who were your allies and who were your enemies?

How have differences between interest groups in herbal medicine come together?

Which organisations/individuals would you say have had a significant influence?

Apart from yourself/your organisation, who would you consider to be the other key stakeholders with an interest in or influence over the professional regulation of CAM practitioners?

Supplementary questions:

What or who has most influenced your thinking on these issues? Have your views/changed over time?

How do you think professional regulation might change in the future and why?

Conclusions

Any other comments?

Thank for the time.

Explain next steps/follow up.

Appendix 5. Final list of codes used in analysis of documents and interviews

MAIN CODE	SUBCODE	DEFINITION
Professional strategy		Evidence that CAM practitioner groups are actively pursuing strategy of professionalisation, past or existing activities, proposed activities only if proposed by the profession themselves
	Professional associations	Evidence of establishment of professional organisations involved in regulation, when were they established and how do they relate formally to other organisations e.g. umbrella body
	Body of knowledge	Evidence of activities to establish body of knowledge and evidence base for CAM practice such as national occupational standards, scientific journal or research
	standards	Evidence of activities to establish unified standards of practice e.g. national occupational standards among CAM practitioners.
	Training courses	Growth in number of training courses on offer and number of educational establishments offering CAM courses
	Voluntary accreditation of training	The presence of a system of accreditation of courses meeting certain minimum standards
	Established voluntary regulation	The presence or absence of systems of voluntary regulation
	Code of ethics	Presence of a code of ethics or standards of practice
	Complaints	Existence of a formal public complaints procedure
SSR		Explicit statement of SSR as an objective
	Public demand	Public demand for regulation
	Mobilisation	Measures of influence such as financial resources, public mobilisation, or representativeness of practitioners
	Mobilisation/Unified among practitioners	The extent to which groups of CAM practitioners were organisationally unified in order to pursue professionalisation
	Mobilisation/Unified among practitioners/Fragmented	Use of words 'fragmented' or 'fragmentation' to describe CAM practitioner groups
	Mobilisation/Unified among practitioners/Consensus	Use of the term consensus to describe within group dynamics of CAM practitioner groups

MAIN CODE	SUBCODE	DEFINITION
	Mobilisation/Unified among practitioners/Divisions	Disagreements or differences about knowledge base, approaches and setting within a particular CAM therapy, e.g. between traditional and western acupuncture, Ayurvedic and western herbal medicine, etc.
	Mobilisation/Unified among practitioners/Diverse	Divisions within CAM generally between different therapies (NOT within CAM therapies which would be under code 'divided')
	Mobilisation/Unified among practitioners/Unified	Use of terms unity, unified, united in relation to state of CAM practitioner groups
	Mobilisation/Unified among practitioners/Medical vs. non med	Division between those who practice who are medically qualified and those who practice and are considered lay or non-medical
	Mobilisation/Active in seeking SSR	Examples where regulation was initiated by the practitioners groups
Professional identity		How CAM practitioner groups perceive the advantages and disadvantages of gaining professional status.
	Benefits	Perceived benefits of professionalisation to CAM practitioners
	Benefits/Access	Regulation will increase access to CAM services for patients particularly on the NHS
	Benefits/Recognition	Regulation will increase status, legitimacy and recognition of the profession, including by orthodox medical profession
	Benefits/Public confidence	Regulation will lead to increased public confidence in and understanding of CAM practice
	Benefits/Interest group	Regulation will enable CAM practitioners to operate as a more effective interest group
	Benefits/interests of practitioners	General view that regulation to the benefit of practitioners but also specific benefits to practitioners of achieving closure.
	Benefits/interests of practitioners/Dispensing rights	Statutory regulation (particularly of herbalists) would ensure restricted access to potent drugs by limiting dispensing rights
	Disadvantages	Perceived disadvantages of professionalisation to CAM practitioners
	Disadvantages/restrict access	Regulation will reduce numbers of practitioners and as a consequence reduce access and consumer choice

MAIN CODE	SUBCODE	DEFINITION
	Disadvantages/domination	Regulation will reduce autonomy and bring CAM practitioners under the domination of doctors
	Disadvantages/standardisation of practice	Regulation will restrict freedom to practice therapy individually through standardisation of practice
	Disadvantages/threatened	Regulation provokes fear among CAM practitioners or feel threatened by it in general
	Disadvantages/expense	Regulation may lead to increases in costs for individual practitioners
Market failure		Arguments made to justify the regulation of CAM practitioners which relate to market failure
	Choice	Regulation should support informed choice rather than restrict choice
	Consumer information	Problems of lack of consumer information and the need for regulation to enhance informed choice of CAM consumers
	Protection of title	The contribution of protection of title to better consumer choice
Risk regulation		Arguments made to justify the regulation of CAM practitioners which relate to minimisation of risks to public health
	Public protection	Ideas relating to why regulation is important. Patient safety, public protection and safeguarding public were all used to search documents for relevant passages.
	Size of problem	Understanding of the size of the problem
	adverse events	Discussion of adverse events
	Types of risk	How risk is defined
	Indirect risks	Risks that arise as a result of a person consulting a CAM practitioner but not from the treatment itself
	Indirect risks/Alt clinical system	Risk that because therapy based on alternative clinical system will not get appropriate treatment
	Indirect risks/unskilled	Risk that arises because the practitioner is not skilled
	Indirect risks/insurance	Risk that the CAM practitioner does not have any personal liability insurance, in the event of suing for damages
	Indirect risks/Conduct	Risk of misconduct by the CAM practitioner
	Indirect risks/Appropriate referral	Risk that the CAM practitioner does not know the limits of their competence and does not appropriately refer to other

MAIN CODE	SUBCODE	DEFINITION
		health practitioners, may delay or deny access to orthodox treatment
	Indirect risks/Misdiagnosis	Risk that the CAM practitioner will misdiagnose the illness (and consequently inappropriate treatment recommended)
	Indirect risks/False claims	Risk that the CAM practitioner makes false claims or at least claims benefits beyond the evidence
	Indirect risks/Conflict of interest	Risk that the CAM practitioner will not act in the interests of patients because of a conflict of interests such as financial gain from selling a product
	Direct risks	Risks that are inherent in some way to the therapy or arise as a direct result of the application of the treatment.
	Direct risks/Physical	Risk of direct physical harm to the patient caused by the CAM practitioner
	Direct risks/Physical/invasive	Risk associated with the invasive nature of the CAM therapy (especially of acupuncture needling).
	Direct risks/Physical/potency	Risk associated with the strength of the CAM treatment (usually herbal medicines or other remedies)
	Direct risks/Physical/toxicity	Risk associated with the contamination or poor quality of CAM products (usually herbal medicines or natural remedies)
	Direct risks/Physical/Infection	Risk of infection through application of CAM technique (usually acupuncture needling)
	Direct risks/wrong use	Risk arising from the misuse of certain treatments, i.e. no evidence for use on certain illnesses/ patients
	Direct risks/emotional harm	Risk of direct emotional or psychological harm to the patient caused by the CAM practitioner
	Direct risks/Contraindications	Risk of interactions with other medications or treatments
	Direct risks/unintended effects	Risk of unintended effects of the CAM treatment due to poor research and/or understanding of the treatment mechanism
	Evidence	Evidence base needed in order to justify regulation
Policy networks		How does the policy community operate, how was the policy initiated and by whom.
	policy community	Descriptions of who is involved in the policy process

MAIN CODE	SUBCODE	DEFINITION
	Key individuals	Role of key individuals in shaping the policy process
	Key individuals/HRH POW	Role of HRH Prince of Wales in shaping policy process
	With government	Relationship with government
	With orthodox	Relationship with orthodox medicine
	With Foundation	Relationship with the Foundation
	With public and consumers	Relationship with the public and consumers
	With members	Relationship of professional bodies with members
	Stakeholders/GB Interviewees	People suggested by GB for Round 1 interviews
	With regulators	Relationship with regulators
Style of process		The style of the policy process, how the policy process is described by actors
	Speed	Speed at which policy process moved
	inclusive	The extent to which the process of developing regulation is inclusive and consultative
	top down	Examples where regulation policy was initiated or actively shaped by state or government actors including government support for legislation
	top down/house	Use of the phrase 'get one's house in order' or similar
	State as creator	Examples where government has played an active role in the creation of CAM practitioner groups
Ideas		Ideas about regulation
	Types of regulation	Ideas about the type of regulation
	Types of regulation/Voluntary	Ideas about voluntary regulation (as opposed to statutory or mandatory)
	Types of regulation/Self regulation	Ideas about the role of professional self-regulation (as opposed to external or state regulation)
	Types of regulation/Statutory	Ideas about statutory regulation, its advantages and disadvantages and whether it is appropriate for CAM practitioners
	Types of regulation/Protection of title	Protection of title or protection of function
	Types of regulation/Consumer Protection	Consumer protection legislation governing advertising, marketing and claims that are made by products. Can be enforced through trading standards officers.

MAIN CODE	SUBCODE	DEFINITION
	Types of regulation/Information	Mandatory information for patients and the public about qualifications, insurance status, prices, etc.
	Types of regulation/Liability	Ideas about the role of liability and mandated insurance
	Types of regulation/Guidelines	Clinical guidelines to regulate the appropriate use of CAM for different patients (especially within the NHS)
	Types of regulation/Education	Official guidelines or standards of training for orthodox medical practitioners practising CAM and CAM practitioners
	Types of regulation/Incentives	Ideas about the role of incentives
	How to structure	Ideas about how a regulatory body should be organised and structured include whether there should be lay representation, mono-disciplinary or multi professional, what subcommittees
	How to structure/Shared Council	Bring together different CAM therapies under a single regulatory body
	How to structure/Single Council	Ideas about whether to have a Single Council for each therapy
	How to structure/Transregulatory	Allow practitioners registered with one statutory body to be regulated in their practice of other modalities through cooperation across regulatory bodies or have dual registration.
	Functions	Ideas about the functions that regulatory bodies should perform in relation to the practice and practitioners
	Functions/Occupational Standards	Set minimum standards of practice (rather than standards for training)
	Functions/Training~education	Set standards for training and education.
	Functions/Training~education/CPD	Set requirements for continuing professional development
	Functions/Training~education/Integration with medicine	Set training standards which include biomedical training
	Functions/Discipline~conduct	Draw up codes of conduct, ethical codes and implement disciplinary procedures
	Functions/Research	Promote and fund research
	Functions/Register	Register practitioners
	Functions/Information provider	Provide information
	Functions/accreditation	accredit training courses
	Functions/Health and Safety	Check practitioners and facilities meet Health and Safety standards

MAIN CODE	SUBCODE	DEFINITION
	Functions/Insurance	Provide mechanisms for ensuring/providing indemnity insurance held by practitioners
	Functions/Complaints	Have in place complaints procedure for patients and the public
	Functions/Language	Check language capabilities of practitioners
	Functions/Professional representation	Represent professional interests
	How	Ideas about how regulation should operate. Not the institutional arrangements but rather the descriptors of the process of regulation. Normative
	How/Accountable	Regulatory mechanisms must ensure public accountability
	How/Responsive	Regulatory mechanisms must be responsive and flexible to changing circumstances
	How/Proportionate	Regulatory mechanisms must be proportionate, should avoid over-regulation
	How/Public confidence	Regulatory mechanisms must have the confidence of the general public
	How/Objective	Regulatory mechanisms must operate objectively and with independence
	How/Transparent	Regulatory mechanisms should be transparent
	How/Accessible	Regulatory mechanisms must be accessible to the public and patients
	How/Fair	Regulatory mechanisms should operate fairly, especially in disciplinary proceedings
	How/Effective	Regulatory mechanisms should be effective
	How/consultative	Regulatory bodies should develop policies and rules in consultation and collaboration with other stakeholders
	How/Fair representation	Structure governing board of regulatory body so that it is representative of all interests within the profession
	Outcomes	Ideas about the outcomes of regulation
	Outcomes/Quality	The benefits of statutory regulation will be to ensure safer and high quality CAM practitioners
	Outcomes/Competence	Positive benefits of regulation helping to enable patients to access competent CAM practitioners
	Outcomes/Integration	Integration as a possible outcome of regulation

MAIN CODE	SUBCODE	DEFINITION
	Which therapies	Ideas about which CAM therapies should be regulated and which ones not
	Source	Where do ideas come from?
	Source/modelled	Path of regulatory development is modelled explicitly on existing regulation either of osteopaths and chiropractors, or other longer established professions.
	Source/comparisons	Model of regulation is developed based on understanding of what goes on in another country. Comparative policy development.
Current situation		The current situation of CAM practice in the UK as described by actors
	Consumer demand	Utilisation levels of CAM and consumer demand for therapies
	Research	Current state of research among CAM therapies
	Medical education	Current role of CAM in the medical curriculum
	Legal	Current legal situation of CAM in the UK
	Legal/Scope of practice	Scope of practice currently permitted by UK law
	Legal/Local authority licensing	Provisions to require licensing of premises by local authorities for certain activities
	NHS provision	The integration of CAM in NHS provision, or the availability of CAM on referral from the NHS
	Numbers of practitioners working patterns	Descriptions of number of practitioners Patterns of employment of CAM practitioners
	Evidence base	The presence of absence of an evidence base
Context		Contextual factors which have played a role in the development of regulation for CAM practitioners (external to the direct policy process)
	UK policy developments	Other areas of government policy which have interacted with the development of policy on CAM regulation
	EU policy developments	Developments in EU policy in relation to CAM, traditional medicines, professional mutual recognition, etc which have had an impact on national debates about regulation
	Major events	Key events or publications which are identified by interviewees as being significant factors in the development of professional regulation

Appendix 6. Recommendations on 'Regulation' and 'Education and training'.

Extract from the House of Lords' Sixth Report

Regulation (Chapter 5)

6. We recommend that, in order to protect the public, professions with more than one regulatory body make a concerted effort to bring their various bodies together and to develop a clear professional structure (para 5.12).

7. We recommend that each of the therapies in Group 2 should organise themselves under a single professional body for each therapy. These bodies should be well promoted so that the public who access these therapies are aware of them. Each should comply with core professional principles, and relevant information about each body should be made known to medical practitioners and other healthcare professionals. Patients could then have a single, reliable point of reference for standards, and would be protected against the risk of poorly-trained practitioners and have redress for poor service (para 5.23).

8. It is our opinion that acupuncture and herbal medicine are the two therapies which are at a stage where it would be of benefit to them and their patients if the practitioners strive for statutory regulation under the Health Act 1999, and we recommend that they should do so. Statutory regulation may also be appropriate eventually for the non-medical homeopaths. Other professions must strive to come together under one voluntary self-regulating body with the appropriate features outlined in Box 5, and some may wish ultimately to aim to move towards regulation under the Health Act once they are unified with a single voice (paras 5.53 and 5.55).

9. We recommend that each existing regulatory body in the healthcare professions should develop clear guidelines on competency and training for their members on the position they take in relation to their members' activities in well organised CAM disciplines; as well as guidelines on appropriate training courses and other relevant issues. In drawing up such guidelines the conventional regulatory bodies should communicate with the relevant complementary regulatory bodies and the Foundation for Integrated Medicine to obtain advice on training and best practice and to encourage integrated practice (para 5.79).

10. We encourage the bodies representing medical and non-medical CAM therapists, particularly those in our Groups 1 and 2, to collaborate more closely, especially on developing reliable public information sources. We recommend that if CAM is to be practised by any conventional healthcare practitioners, they should be trained to standards

comparable to those set out for that particular therapy by the appropriate (single) CAM regulatory body (para 5.83).

11. We recommend that the MCA find a mechanism that would allow members of the public to identify health products that had met the stringent requirements of licensing and to differentiate them from unregulated competitors. This should be accompanied by strong enforcement of the law in regard to products that might additionally confuse the customer with claims and labelling that resemble those permitted by marketing authorisations (para 5.93).

12. We strongly recommend that the Government should maintain their effective advocacy of a new regulatory framework for herbal medicines in the United Kingdom and the rest of the European Union, and urge all parties to ensure that new regulations adequately reflect the complexities of the unregulated sector (para 5.95).

13. We are concerned about the safety implications of an unregulated herbal sector and we urge that all legislative avenues be explored to ensure better control of this unregulated sector in the interests of the public health (para 5.97).

14. We support the view that any new regulatory regime should respect the diversity of products used by herbal practitioners and allow for simplified registration of practitioner stocks. Nevertheless, any such regime must ensure that levels of quality and assurance of safety are not compromised (para 5.98).

Professional Training and Education (Chapter 6)

15. Establishing an independent accreditation board along the lines of the British Acupuncture Accreditation Board is a positive move. Other therapies with fragmented professional representation may wish to use this as a model (para 6.20).

16. We recommend that CAM training courses should become more standardised and be accredited and validated by the appropriate professional bodies. All those who deliver CAM treatments, whether conventional health professionals or CAM professionals, should have received training in that discipline independently accredited by the appropriate regulatory body (para 6.33).

17. We suggest that the CAM therapies, particularly those in our Groups 1 and 2, should identify Continuing Professional Development in practice as a core requirement for their members (para 6.34).

18. We consider that it is imperative that higher educational institutions and any regulatory bodies in CAM liaise in order to ensure that training is adequate for registration. If extra training is required after academic qualification to ensure fitness to practise, this should be defined by the appropriate professional body, which should then implement appropriate mechanisms in order to see that this objective is achieved (para 6.40).

19. We recommend that training in anatomy, physiology and basic biochemistry and pharmacology should be included within the education of practitioners of therapies that are likely to offer diagnostic information, such as the therapies in Groups 1 and 3a. Although it may be useful for other therapists to understand basic biomedical science, there is no requirement for such in-depth understanding if the therapy being practised is to be used as an adjunct to conventional medicine (para 6.43).

20. We recommend that every therapist working in CAM should have a clear understanding of the principles of evidence-based medicine and healthcare. This should be a part of the curriculum of all CAM therapy courses. An in-depth understanding of research methods may be even more important for those therapies that operate independently of medical supervision, and which attempt to make a diagnosis and to cure complaints rather than for those which offer relaxation or aim to improve the general quality of life of patients. Therefore training in research and statistical methods may be particularly appropriate for practitioners of therapies in Groups 1 and 3a. But we consider that an understanding of research methods and outcomes should be included in the training of all CAM practitioners. It is important that all of those teaching these courses should understand these principles (para 6.49).

21. We recommend that all CAM training defines limits of the particular therapist's competence as clearly as possible in the state of current knowledge. Training should also give students clear guidance on when a patient should be referred to a primary care physician or even directly to secondary hospital care (para 6.52).

22. We recommend that all CAM therapists should be made aware of the other CAM therapies available to their patients and how they are practised. We do not think it should be assumed that CAM practitioners competent in one discipline necessarily understand the others (para 6.54).

23. We conclude that there should be flexibility for training institutions to decide how to educate practitioners. It is the relevant professional regulatory body of a specific CAM therapy that should set objectives of training and define core competencies appropriate to

their particular discipline, and we so recommend. We do not advocate a blanket core curriculum (para 6.61).

24. We recommend that, whether subject to statutory or voluntary regulation, all healthcare regulatory bodies should consider the relevance to their respective professions of those elements set out in paragraph 6.55 (para 6.62).

25. We recommend that therapies with a fragmented professional organisation work with Healthwork UK to develop National Occupational Standards, and we encourage the Department of Health to further support Healthwork UK's activity with such therapies; we believe that this would be of long-term benefit to the public (para 6.70).

26. We recommend that familiarisation should prepare medical students for dealing with patients who are either accessing CAM or have an interest in doing so. This familiarisation should cover the potential uses of CAM, the procedures involved, their potential benefits and their main weaknesses and dangers (para 6.77).

27. We recommend that every medical school ensures that all their medical undergraduates are exposed to a level of CAM familiarisation that makes them aware of the choices their patients might make (para 6.79).

28. We recommend that Royal Colleges and other training authorities in the healthcare field should address the issue of familiarisation with CAM therapies among doctors, dentists and veterinary surgeons by supporting appropriate Continuing Professional Development opportunities (para 6.85).

29. The General Osteopathic and Chiropractic Councils, and any other regulatory bodies, should develop schemes whereby they accredit certain training courses aimed specifically at doctors and other healthcare professionals, and which are developed in conjunction with them. Similar schemes should be pursued by dentists and veterinary surgeons (para 6.95).

30. We recommend that the UKCC work with the Royal College of Nursing to make CAM familiarisation a part of the undergraduate nursing curriculum and a standard competency expected of qualified nurses, so that they are aware of the choices that their patients may make. We would also expect nurses specialising in areas where CAM is especially relevant (such as palliative care) to be made aware of any CAM issues particularly pertinent to that speciality during their postgraduate training. The Royal College of Nursing and the UKCC, as they do not provide CAM training themselves, should compile a list of courses in CAM that they approve, in order that nurses who wish to practise in this field can obtain guidance on appropriate training (para 6.106).

Appendix 7. Membership of the Acupuncture Regulatory Working Group and the Herbal Medicine Regulatory Working Group

Acupuncture Regulatory Working Group

Lord Chan, Chair

Stephen Halpern, Secretary

Acupuncture Professional Representatives

Joan Davies, Acupuncture Association of Chartered Physiotherapists

Val Hopwood, Acupuncture Association of Chartered Physiotherapists

Peter Dowds, British Academy of Western Acupuncture

Paul Mayer, British Academy of Western Acupuncture

Jasmine Uddin, British Acupuncture Council

John Wheeler, British Acupuncture Council

Anthony Campbell, British Medical Acupuncture Society

Mike Cummings, British Medical Acupuncture Society

Lay members

Mercy Jeyasingham, Lay Member

Alaba Okuyiga, Lay Member

Kathleen Wood, Lay Member

Observers

Gordon Brown, Complementary Therapies Team, Department of Health

Rebecca Sidwell, Health Regulatory Bodies Branch, Department of Health (from April 2003)

Pamela Jack, The Prince of Wales's Foundation for Integrated Health

Herbal Medicine Regulatory Working Group

Professor R Michael Pittilo, Chairman and Lay Member

Andrew Chevallier, Vice Chair

Amrit Ahluwalia, Secretary

Herbal Professional Representatives and Alternates

Dee Atkinson/Peter Conway, College of Practitioners of Phytotherapy

Jill Davies/Peter Jackson-Main, Association of Master Herbalists

Alison Denham/Trudy Norris, National Institute of Medical Herbalists

Peter Jackson-Main/Jill Davies, European Herbal Practitioners Association

Dr Song Xuan Ke/Geoff Most, British Society of Chinese Medicine

Dr Nick Lampert/Emma Farrant, Register of Chinese Herbal Medicine

Dr Graeme Litchfield/Ifanca James, International Register of Consultant Herbalists

Elizabeth Lyden/Ed Berger, Unified Register of Herbal Practitioners

Dr N Moorthy/Dr Athique, Ayurvedic Medical Association

Professor Huijun Shen/Ji Dong Wu, Association of Traditional Chinese Medicine

Dr S Warriar/Dr D Gunawant, British Association of Accredited Ayurvedic Practitioners
and British Ayurvedic Medical Council

Lay Members

Sally Hornsby, Lay Member

Robert Johnstone, Lay Member

Mee Ling Ng, Lay Member

Non-Herbal Professional Body Representatives

Professor Bill Dawson, Royal Pharmaceutical Society and Lay Member

Dr Catherine O'Sullivan, Education Committee, European Herbal Practitioners
Association

Herbal Medicine Sub-Committee

Michael McIntyre, Chair

Members

Dee Atkinson

Bill Dawson

Professor H Shen

Dr S Warriar

Amrit Ahluwalia

Stakeholder Representatives

Gordon Brown, Complementary Therapies Unit, Department of Health

Rebecca Sidwell, Health Regulatory Bodies Branch, Department of Health (from April 2003)

Pamela Jack, The Prince of Wales's Foundation for Integrated Health

Michael McIntyre, European Herbal Practitioners Association

Appendix 8. Biographical details of members of the policy network

Thomas Bingham, Baron Bingham of Cornhill, KG, PC: Lord Chief Justice of England and Wales 1996-2000, Chair King's Fund Working Party on Osteopathy and King's Fund Working Party on Chiropractic; formerly practised from Fountain Court Chambers in London; Chairman of the British Institute of International and Comparative Law; High Steward of the University of Oxford

Frances Blunden: Principal Policy Advisor, Which? Formerly Director of POPAN (Prevention of Professional Abuse Network); formerly worked at National Consumer Council; active member of her local Community Health Council; lay member of the Council for Professions Supplementary to Medicine (2001-2002); consumer representative on the Clinical Disputes Forum.

Gordon Brown: civil servant at the Department of Health, policy lead on complementary therapies within the Public Health Directorate; retired August 2004.

Steve Catling: civil servant at the Department of Health; Head of Professional Standards and Pensions, Department of Health

Professor Sir Graeme Catto MD: Professor in the College of Life Sciences and Medicine, University of Aberdeen; President of the General Medical Council appointed by the Council of Heads of Medical Schools 2001 took office on 1 February 2002; Formerly Vice-Principal at King's College London, Dean of the Guy's, King's and St Thomas' Medical & Dental Schools and Pro-Vice Chancellor of the University of London; knighted in 2002 for services to medicine and medical education; member of the GMC Council (November 1994-present); honorary physician with an interest in renal medicine; a member of the Council for the Regulation of Healthcare Professionals; a member of SE London Strategic Health Authority.

Lord Chan of Oxton: Appointed to the Lords' in 2001; died aged 65 in February 2006; only peer of Chinese origin; Professor of Ethnic Health Liverpool University; lecturer and consultant at the Liverpool School of Tropical Medicine; formerly lecturer and consultant paediatrician at the University of Singapore; formerly director of the Leeds-based NHS Ethnic Health Unit (1994-1999); Director of two successive north-western primary health trusts; Contributed to the Commission on the Future of Multicultural Britain; Member of the Press Complaints Commission (2002-2006); Chairman of the Overseas Christian Mission

Nigel Clarke: Chair of the General Osteopathic Council (since May 2001); a lay member GOsC since its inception and Treasurer (1997-2001); member of the Council for Healthcare Regulatory Excellence; trustee of the Prince of Wales Foundation for Integrated Health; senior partner of Learned Lion Partners ; formerly at the Special Programmes Unit of the CBI, the House of Commons, Conservative Research Department.

Jonathan Coe: Chief Executive POPAN (Prevention of Professional Abuse Network)

Michael Cummings: full-time Medical Director of the British Medical Acupuncture Society (BMAS) since 2000; an honorary clinical specialist at the Royal London Homeopathic Hospital; formerly a medical officer in the Royal Air Force (RAF); Member Acupuncture Regulatory Working Group; Member, Steering Group on statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners.

Dr Michael Dixon: Devon GP for 21 years; Chair of NHS Alliance (since 1998); Senior Associate at the King's Fund; Honorary Senior Fellow in Public Policy at HSMC Birmingham University; Honorary Senior Lecturer in Integrated Healthcare at the Peninsula Medical School; Member, Steering Group on statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners.

Professor Edzard Ernst: Laing Chair in Complementary Medicine, University of Exeter (1993-present), qualified doctor (Germany); training in acupuncture, autogenic training, herbalism, homoeopathy, massage therapy and spinal manipulation; formerly Professor in Physical Medicine and Rehabilitation (PMR) at Hanover Medical School and Head of the PMR Department at the University of Vienna.

Simon Fielding OBE: trained as an osteopath; first chairman of the General Osteopathic Council; Department of Health special adviser on complementary medicine since 1993; trustee of Demelza House Children's Hospice; Co-Chairman of the Regulation Steering Group and Member of Steering Committee, Prince of Wales's Initiative on Integrated Medicine.

Peter Fisher: Vice President of the Faculty of Homeopathy; Clinical Director for the Royal London Homeopathic Hospital, Editor of British Homeopathic Journal.

Michael Fox: Chief Executive of the Foundation for Integrated Health (1998-2005); previously worked in NHS for 21 years latterly as Chief Executive of City and Hackney NHS Trust and before that a FHSA; trustee for a mental health charity; non-executive director of the Medicines & Healthcare products Regulatory Agency.

Stephen Gordon: Vice-chair of the Council of Organisations Registering Homeopaths; a member of the British Acupuncture Accreditation Board; founder, and current general secretary of the European Council for Classical Homeopathy; former Director, Society of Homoeopaths; Member of Regulation and Education and training Working Group, Prince of Wales's Initiative on Integrated Medicine;

Stephen Holgate: MRC Clinical Professor of Immunopharmacology, University of Southampton; Trustee of the Prince's Foundation for Integrated Health; Honorary Consultant Physician, Southampton General Hospital; Chairman Research and Development Working Group and Member of Steering Committee, Prince of Wales's Initiative on Integrated Medicine; special adviser to the House of Lords S&T Sub-Committee on CAM 2000 – 2001; established Royal College of Physicians sub-committee on complementary medicine.

Valerie Hopwood: Research Fellow, Complementary Medicine Research Unit, University of Southampton; Member, Steering Group on statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners; Member, Acupuncture Regulatory Working Group; Education Officer, Acupuncture Association of Chartered Physiotherapists; Member of Education and training Working Group, Prince of Wales's Initiative on Integrated Medicine.

HRH the Prince of Wales: Patron or President of around 380 organisations; President of the King's Fund (from 1st January 1986- present); President of the British Medical Association (1982-1983); personally founded 15 charities including The Prince's Foundation for Integrated Health (since 1993).

Pamela Jack: Standards Programme Manager (formerly Regulation Programme Manager) at the Foundation for Integrated Health (2000-2006); a background in Health Promotion and Health Service Management.

Dr Bob Leckridge B.Sc M.B., Ch.B., M.F.Hom., F.F.Hom: President of the Faculty of Homoeopathy (1998-2005); Associate Specialist at Glasgow Homeopathic Hospital; qualified general practitioner; National and International Clinical Examiner for the MFHom (Membership of the Faculty of Homeopathy) exam (1993 – present)

George Lewith: Founder Complementary Medicine Research Unit, Southampton University; Senior Research Fellow within the Department of Primary Care, Southampton University; Member of the Research & Development Working Group and Steering Committee, the Prince of Wales's Initiative on Integrated Health; Co-Director, Centre for the Study of Complementary Medicine, Southampton; Hon Senior Lecturer, University of

Southampton; established Royal College of Physicians sub-committee on complementary medicine

Robert Maxwell: Chief Executive King's Fund (1980-1997); Chair Gloucestershire Partnership NHS Trust; Governor of the National Institute of Social Work; Member of the Prince of Wales Advisory Group on Disability; Trustee, Joseph Rowntree Memorial Foundation and World Health Organization Special Adviser on a number of assignments and President of the Association for Quality in Healthcare

Michael McIntyre: Chairman, European Herbal Practitioner Association; Chair Herbal/Traditional medicine stakeholder group (2005-); Principal School of Chinese Herbal Medicine; herbalist trained in western herbalism, traditional Chinese herbal medicine and acupuncture; formerly president of the National Institute of Medical Herbalists; Member of Education and training Working Group, Prince of Wales's Initiative on Integrated Health.

Simon Mills MCPP, FNIMH, MA: Director of Centre for Complementary Health Studies, Exeter University; special adviser to the House of Lords S&T Sub-Committee on CAM; herbal medicine practitioner; co-author with Sarah Budd of reports for Department of Health; Chair Reflexology Forum, hosted by FIM; Co-Chairman of the Regulation Steering Group and Member of Steering Committee for The Prince of Wales's Initiative on Integrated Medicine; Chairman, British Herbal Medicine Association; Secretary, European Scientific Cooperative On Phytotherapy (ESCOP); past President of NIMH; first President of CCAM (1986)

Michael O'Farrell: Chief Executive of the British Acupuncture Council; Chair, Chinese medicine stakeholder group (2005-); formerly senior manager with the Eastman Kodak Company.

Professor David Peters: Professor of Integrated Healthcare and Clinical Director of the School of Integrated Health at the University of Westminster; Trustee of the Prince's Foundation for Integrated Health; a medical doctor; a registered osteopath (1987); a member of the Faculty of Homeopathy; formerly a GP at Marylebone Health Centre; Lecturer in general practice at St Mary's Hospital Medical School; Member of the Steering Committee and Chairman of the Delivery Mechanisms Working Group, the Prince of Wales's Initiative on Integrated Health; Chair of the British Holist Medical Association

Michael Pittilo: Principal of Robert Gordon University in Aberdeen; Chair, Steering Group on statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners (2005-); Chair Herbal Medicine Regulatory Working Group (2002-

2004); formerly Vice Chancellor University of Hertfordshire, Hatfield; formerly Dean of Joint Faculty of Healthcare Sciences, Kingston University and St George's Hospital Medical School; Member of Education and training Working Group, Prince of Wales's Initiative on Integrated Medicine; Trustee Prince of Wales's Foundation for Integrated Health.

Professor Mike Saks PhD: Pro-Vice Chancellor (Research and Academic Affairs), University of Lincoln; formerly Dean of the Faculty of Health and Community Studies at De Montfort University; Chair of the Research Council for Complementary Medicine; member of the National Cancer Research Institute Complementary Therapies Clinical Studies Development Group; member of the Expert Panel for the Department of Health National Centre for Research Capacity Development Personal Awards Scheme and the new Department of Health Complementary and Alternative Medicine Research Policy Committee. Member of Delivery Mechanisms Working Group, Prince of Wales's Initiative on Integrated Medicine;

Rebecca Sidwell: civil servant at the Department of Health; led on CAM regulation within the Health Regulatory Bodies Branch within the Human Resources Directorate (April 2003-August 2004)

Julie Stone: Deputy Director of the Council for Healthcare Regulatory Excellence (until January 2007); Visiting Professor in Health Care Ethics at the University of Lincoln, School of Health and Social Care; member of the Clinical Disputes Forum Committee; Member, Steering Group on statutory regulation of acupuncture, herbal medicine and traditional Chinese medicine practitioners; member of, and consultant to, the Prince of Wales' Foundation For Integrated Health Regulatory Action Group; formerly Lecturer in Ethics and Law, Birmingham; Member of Regulation Working Group, Prince of Wales's Initiative on Integrated Health; barrister by training; formerly worked for Hempsons Solicitors,.

David Tredinnick MP: Conservative MP for Bosworth since 1987; Joint-Chairman of the All-Party Parliamentary Group for Integrated and Complementary Healthcare since 2002 (formerly Treasurer 1989-2002); Member of Standing Committees for the 1993 Osteopaths' Act and the 1994 Chiropractors' Act.

Maggie Wallace: Chair CORH (until 2006); consultant on a range of professional standards issues in health and education; Formerly Director of Standards Promotion, UKCC; Non-Executive Director and Chair of the Clinical Governance Board, North Hampshire Hospitals Trust

Lord Walton of Detchant: Appointed to the House of Lords in 1989; Patron of Healthwatch; Former member of Council for POWFIH; President of the BMA; President of the GMC 1982-1989 (7 year limit); member of the General Medical Council for 18 years; Chair of the Lords Select Committee on Science and Technology subcommittee on CAM; Member of the Lords select Committee on Science and Technology; formerly a neurologist, Dean of Medicine at the University of Durham; President of the Royal Society of Medicine; President of the World Federation of Neurology.

Richard Woodfield: Group Manager, European Support And Review Of Herbal Policy, MHRA (Medicines)

Appendix 9. Trustees of the Prince of Wales's Foundation for Integrated Health

Chairman

Sir Michael Peat began his career as an accountant at KPMG, before joining the Royal Household in 1993. He has held the titles of Keeper of the Privy Purse, Treasurer to HM The Queen and Receiver General of the Duchy of Lancaster. He was appointed as Private Secretary to HRH The Prince of Wales in 2002. He is a trustee to the Royal Collection Trust and Historic Royal Palaces Trust.

Trustees

Nigel Clark is managing director of Weber Shandwick/GJW Public Affairs. Previously director of GJW Government Relations Limited, of Primary Care Group Holdings plc and a researcher in politics and industry. He has been chair of the General Osteopathic Council since May 2001, having been a lay member since its inception. He is now also a non-executive member of the new regulators authority.

Dr Michael Dixon has been a full-time GP for 18 years. He was a co-founder of the Mid-Devon Commissioning Group and the National Commissioning Movement and, since 1998, he has been chair of the NHS Alliance. His national appointments include roles on the National Quality Taskforce and Cabinet Committee on Bureaucracy. He is an honorary research fellow at Exeter University, has published a number of papers on complementary medicine and is currently part of a group researching into the therapeutic relationship.

Simon Fielding OBE originally trained as an osteopath and was the principal architect of the Osteopaths Act 1993. He was the first chairman of the General Osteopathic Council and has been the Department of Health's special adviser on complementary medicine since 1993. He is also a trustee of Demelza House Children's Hospice.

Rosalind Mary Foster is a barrister with a practice in the field of professional regulation and discipline. She was Recorder of the Crown Court 1982 - 1998. With a special interest in ethics and medicine, she was closely involved in the development of new performance

procedures for doctors at the General Medical Council. She has presented hundreds of medical and dental conduct cases to the Privy Council and High Court, including cases concerned with confidentiality, consent, abuse of the professional relationship, indecency and fraud.

Nicholas Gold is Managing Director at ING Investment Bank. He has previously worked at Touche Ross & Co. and as a solicitor at Freshfields. He is a fellow of the Institute of Chartered Accountants, a council member of RADA and is chair of their Finance and General Purposes Committee.

Stephen Gordon has practised homeopathy since 1981 and is a past chair of the Society of Homeopaths. He is vice-chair of the Council of Organisations Registering Homeopaths, a member of the British Acupuncture Accreditation Board and is a founder, and current general secretary of the European Council for Classical Homeopathy.

Professor Stephen Holgate is MRC clinical professor of immunopharmacology at the University of Southampton. He is a member of several government committees, and a past member of the NHS Central Research & Development Committee. He was an advisor to the House of Lords Select Committee on Science and Technology enquires into complementary and alternative medicine 2000 - 2001.

Michael McIntyre is a herbalist trained in western herbalism, traditional Chinese herbal medicine and acupuncture. Formerly president of the National Institute of Medical Herbalists, he currently chairs the European Herbal Practitioners Association.

Professor David Peters is clinical director of the School of Integrated Health at the University of Westminster. Formerly a GP at Marylebone Health Centre and lecturer in general practice at St Mary's Hospital Medical School, he is also a registered osteopath and a member of the Faculty of Homeopathy.

Michael Pittilo is the pro vice-chancellor of the University of Hertfordshire. His career in higher education has also included being the Dean at the Faculty of Health and Social

Sciences at Kingston University and St. George's Hospital Medical school; Dean with responsibility for Multi-professional Education and Training, and Dean with responsibility for post-graduate taught courses, both at St. George's; and appointments abroad. He is a fellow of many organisations including the Institute of Biology, the Royal Society of Health and the Royal Society of Medicine, and is a writer, researcher and speaker on healthcare issues

Anne Wadsworth is a director of Anne Wadsworth Associates, a government and public affairs consultancy specialising in health and environmental matters. A former journalist, she has extensive experience of working in both public and private sectors and has been involved in the integrated healthcare initiative since its conception.

Robert Wilson is Chairman of Nelsonbach, Britain's largest producer of natural medicine. He has spent the majority of his working life involved in the world of complementary and alternative medicine. He is Chairman of BHMA (British Homeopathic Manufacturer Association) in the UK. He is a board member of ECHAMP, the European Coalition for Homeopathic and Anthroposophic Medicine and Products. Robert is also a Trustee of the Scottish Civic Trust.

Source: (Foundation for Integrated Health, 2005)

Appendix 10. Freedom of Information request

Linda Percival
Customer Service Centre
Department of Health
Richmond House
79 Whitehall
London SW1A 2NL

Department of Social Policy

Houghton Street
London WC2A 2AE

Tel 020 7955 7515

Fax 020 7955 6803

Email: a.Dixon@lse.ac.uk

18 September 2007

Dear Ms Percival

Freedom of Information Act

I am writing to make a request for information under the Freedom of Information Act 2000.

I would like to know:

How many letters have been received by the Secretary of State for Health or Ministers of Health from HRH The Prince of Wales or his private office at Clarence House concerning integrated health or complementary and alternative medicine?

When were these letters dated?

Can copies of correspondence since 1990 between the Secretary of State for Health or Ministers of Health and HRH the Prince of Wales on this subject be made available under the FOI Act?

If so please could you make the copies available to me either in hard copy to the above address or electronic copies to my email address.

Yours sincerely

Ms Anna Dixon
Lecturer in European Health Policy

Our ref: TO6026534

Ms Anna Dixon
Department of Social Policy
Houghton Street
London
WC2A 2AE

Richmond House
79 Whitehall
London
SW1A 2NS
Tel: 020 7210 3000

24 August 2005

Dear Ms Dixon


**FREEDOM OF INFORMATION – COMPLEMENTARY AND ALTERNATIVE
MEDICINE**

Thank you for your letter of 23 May requesting, under the Freedom of Information Act, details of correspondence between HRH the Prince of Wales and Health Ministers on the subject of complementary and alternative medicine (CAM).

I am writing to advise you that the Department of Health can neither confirm nor deny that it holds the information you requested as the duty in section 1(1)(a) of the Freedom of Information Act 2000 does not apply, by virtue of section 37(2) of that Act. However, this should not be taken as conclusive evidence that the information you requested exists or does not exist.

In considering the balance of the public interest in this case, we have considered the general public interest in disclosure and the fact that openness in government can increase public trust in and engagement with the government. However, there are also a number of key public interest considerations in favour of neither confirming nor denying that the information is held in this case. It is a fundamental constitutional principle that communications between the heir to the throne and government Ministers, including the fact as to whether any such communications are held by the department, are essentially confidential in nature. The Heir to the throne is in the same constitutional position as the Sovereign in relation to communications with the government: the Sovereign has the right and the duty to counsel, encourage and warn her government and is entitled to have opinions on government policy and to express those opinions to her ministers. It is essential that these communications are, and remain, confidential, to maintain the political neutrality of the Sovereign in public affairs.

As the Heir to the throne is in the same constitutional position, any communications between him and government ministers, including those between their respective private secretaries, are, like those of the Sovereign, likely to remain sensitive because they could, at a later date, be taken to show a lack of political neutrality. In this case,



UK
PRESIDENCY
OF THE EU
2005

the fact of whether or not there have been any such communications, or more specifically whether any such communications are held by a department for the purposes of the Act, is also confidential. Knowledge as to whether or not there were communications on a particular subject at a particular time would betray that essential confidence and, in turn, could affect the political neutrality of HRH the Prince of Wales, his relationship with Government Ministers, or could prejudice the diplomatic activities of the monarch and the heir.

We have therefore concluded that the public interest in neither confirming nor denying whether we hold any information of the type requested by you outweighs the public interest in disclosing whether we hold any such information.

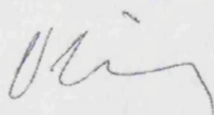
If you are unhappy with the way the Department of Health has handled your request you may ask for an internal review. You should contact the Section Head of the Freedom of Information group at the Department of Health, quoting the reference number above:

Jill Moorcroft
Skipton House
80 London Road
London
SE1 6LH

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,



Victoria Lindsay
Customer Service Centre
Department of Health

Appendix 11. Membership of the House of Lords Select Committee on Science and Technology Sub-Committee I

Inquiry on Complementary and Alternative Medicine

Earl Baldwin of Bewdley (co-opted)

Lord Colwyn (co-opted)

Lord Haskel

Lord Howie of Troon

Lord Perry of Walton

Lord Quirk

Lord Rea

Lord Smith of Clifton (co-opted)

Lord Soulsby of Swaffham Prior (co-opted)

Lord Tombs

Lord Walton of Detchant (Chairman)

Specialist advisers

Professor Stephen Holgate, Clinical Professor of Immunopharmacology, University of Southampton

Mr Simon Mills, Director of the Centre for Complementary Health Studies, University of Exeter.

Declared interests in relation to this inquiry

Earl Baldwin of Bewdley— Joint Chairman of the Parliamentary Group on Alternative and Complementary Medicine; patron of the Natural Medicines Society; patron of the National Federation of Spiritual Healers.

Lord Colwyn— President of the Parliamentary Group on Alternative and Complementary Medicine; President, Natural Medicines Society; President, Arterial Health Foundation; patron of the Research Council for Complementary Medicine; patron of the Blackie Foundation; patron of the Foundation for Traditional Chinese Medicines; patron of the National Federation of Spiritual Healers; Council Member of the Medical Protection Society; Chairman, Dental Protection Ltd; member of the Royal Society of Medicine.

Lord Rea — Former NHS general practitioner; former lecturer in Social (Public Health) Medicine at St Thomas's Hospital Medical School; Fellow of the Royal Society of Medicine (former President of Section of General Practice); Hon. Secretary of National Heart Forum (former Vice-Chairman); Chairman of All-Party Parliamentary Food and Health Forum; Treasurer of All-Party Parliamentary Group on Drug Abuse; Trustee of Action Research; Medicinal Cannabis Foundation; Patron of Connect Foundation for Mental Health; Vice-Patron of Child Psychotherapy Trust, MIND.

Lord Soulsby of Swaffham Prior— President, Royal Society of Medicine (until 18 July 2000); member of a committee which advises the British Veterinary Association on, among other things, alternative medicines and practices.

Lord Tombs— Chairman, Goldsmiths Education Committee, which sponsors courses for A-level science teachers, including a course on complementary and alternative medicine.

Lord Walton of Detchant— Former Professor of Neurology and Dean of Medicine, University of Newcastle upon Tyne; former Warden, Green College, University of Oxford; former President, BMA, Royal Society of Medicine, GMC, Association of British Neurologists and World Federation of Neurology; occasional neuroscience adviser to a pharmaceutical company; patron, Action for Disability, International Spinal Research Trust, National Head Injuries Association (Headway), North Northumberland Day Hospice, Oxford International Biomedical Centre, 'Puff-In' Appeal (cystic fibrosis), Radcliffe Medical Foundation; Vice-Patron, Brendoncare Foundation; President, Hampra, Neurosciences Research Foundation; Vice-President, Epilepsy Research Foundation, Guideposts Trust; Life President, Muscular Dystrophy Group of Great Britain and Northern Ireland; member of the King's Fund Working Party on Osteopathy and Chiropractic.

Lord Winston— Practising medical academic, occasionally using complementary techniques — particularly acupuncture — for patients. Currently conducting a trial of the effect of trace elements on human fertility and miscarriage.