Development of Proposals for a Future Voluntary Regulatory Structure for Complementary Health Care Professions

A Report Commissioned by the Prince of Wales's Foundation for Integrated Health

Professor Julie Stone University of Lincoln School of Health and Social Care

September 2005

Published by: The Prince of Wales's Foundation for Integrated Health 12 Chillingworth Road London N7 8QJ

t 020 7619 6140 e <u>enqiries@fihealth.org.uk</u> w fihealth.org.uk

CONTENTS

Executive Summary	4
Part One: Introduction	7
Part Two: Analysis of Issues	
The Foundation's Regulation Programme	11
House of Lords Select Committee	12
Changes in the Regulatory Landscape	13
Move from Self-regulation to Professionally-led Regulation	18
Best practice in Professionally-led Regulation	19
Part Three: Exploring Regulatory Solutions	
Maintaining status quo	23
Statutory regulation	24
A composite, federal style of regulation	26
A composite, federal structure: Q & A	29
Part Four	
Conclusions	37
Glossary	38
References	41
Annex 1	44
Annex 2	47
Annex 3	48

Author's note: The views expressed in this Report are solely those of the author and do not reflect the opinions or policies of any organisation with which the author is affiliated.

EXECUTIVE SUMMARY

- The public has a right to expect health care services to be provided by appropriately educated, safe, competent and regulated practitioners. All complementary practitioners who work with patients should be subject to effective regulation. Complementary practitioners work unsupervised, often in domiciliary settings, treating potentially vulnerable adults and children.
- 2. Because of the common law freedom to practise, standards of training and practice vary enormously across the sector. The multiplicity of registering bodies and qualification-awarding bodies has made it difficult for patients to identify who is and who is not an appropriate practitioner. Voluntary systems of regulation need to be rationalised and strengthened if members of the public are to be able to make informed choices. A single, publicly available, up-to-date register of qualified practitioners is at the heart of effective regulation.
- 3. Although a statutory 'CAM Council' or other mechanism is to be introduced for acupuncture and herbal medicine, the House of Lords deemed statutory regulation to be unnecessary for the majority of complementary therapies. The House of Lords Select Committee accepted that voluntary regulation was sufficient for the vast majority of complementary therapy professions. There has been little discussion of the *form* that voluntary regulation needs to take to provide maximum public protection. The Prince of Wales's Foundation for Integrated Health ('The Foundation') is committed to supporting the development of an appropriate system of voluntary regulation for identified complementary therapies.
- 4. Regulation has burdens as well as benefits. The predominant burden is assumed by the group whose activities are being restricted, in this case, practitioners. The Government is committed to proportionate and risk-based regulation. Earlier this year, an influential Treasury-commissioned review (the Hampton Review) urged all sectors to reduce the burden of regulation and to make regulation more efficient (1). Outside healthcare, regulators have been merged, and more systematic, risk-based approaches have been adopted. Voluntary regulation similarly needs to avoid duplications and overlaps and should comply with the better Regulation Task Force's five principles of accountability, proportionality, transparency, consistency and targeting.
- 5. Challenges to finding a single regulatory solution are that the eleven therapies accepted by the Foundation onto the next stage of this programme are at differing stages of professional development, are of varying sizes, embrace varying numbers of professional associations, and may have different longer term regulatory aspirations. Educational standards vary considerably within the different schools represented, although National Occupational Standards (NOS) have been developed for most of the professions in question.

- 6. None of the bodies identified for inclusion in the Foundation's programme currently has the financial resources to make a single body approach sustainable. Because resources are limited, the Foundation's funding must be directed towards encouraging a system of voluntary regulation which is efficient and cost-effective, and sustainable in the longer term.
- 7. Regulation of complementary therapies needs to take account of wider developments in health care regulation. The Government's two post-Shipman reviews of regulation are currently exploring initial and ongoing fitness to practise, revalidation and appraisal processes, and mechanisms to harmonise the practices of the nine existing statutory regulators. Other areas under consideration include the extension of regulation/registration to the wider health and social care workforce, the need for consistency and sharing of best practice in regulation, and a review of the functions and number of existing statutory regulators.
- 8. Statutory health care regulation is moving away from separate uniprofessional regulatory bodies, in favour of composite, or federal bodies which regulate several professions. The federal model provides a structure for developing consistent, high standards across a range of practitioners and also facilitates economies of scale. This lets regulators take on the full range of regulatory functions and results in lower registration fees for individual registrants. This model may provide a useful comparator for the complementary health care sector.
- 9. Statutory professionally-led regulation has undergone substantial development in recent years. Critically, professions are now expected to work in partnership with other stakeholders who have a legitimate interest in regulation. Regulatory Councils are now expected to have a significant lay (public) presence. Assumptions and principles underpinning voluntary self-regulation also need to be revisited to reflect current ideas around best practice, including stakeholder representation. Additionally, any voluntary regulation for complementary practitioners needs to take account of practitioners' therapeutic beliefs and holistic ways of working.
- 10. To take voluntary regulation forward it is necessary to explore the relative advantages and disadvantages of the regulatory options open to practitioners. The three realistic options are: (i) maintaining the status quo, allowing the separate professions to continue to come together at their own pace; (ii) statutory regulation, either pursued by a profession itself, or potentially demanded by the Government at some future point on the basis of perceived risk; or (iii) creating a single voluntary regulatory structure, probably in the form of a federal body, which would promote consistent high standards and economies of scale.
- 11. Looking at the available options, the status quo has certain advantages. Significant progress has already been made in bringing these professions closer towards a single register for each profession,

and the independently chaired, profession-specific groups are providing a helpful arena for disagreements to be worked through. However, the professions in question represent some of the most frequently accessed complementary therapies. The lack of quality assurance in the current system poses potential risk to vulnerable patients, including children and vulnerable elders. Many of these risks could be reduced through better regulation. Statutory regulation, whilst still viewed by some complementary practitioners as the ultimate regulatory goal, is not a politically viable option in the current climate, particularly since the Government is actively considering reducing the number of existing health care regulators.

- 12. Taking into account the relative advantages and disadvantages of the possible regulatory options, a federal system of regulation emerges as the best regulatory solution. This model would produce a framework for ensuring consistent, high standards, and provide consumers with a single point of reference if anything goes wrong. It would achieve economies of scale including the capacity to create single mechanisms for accreditation, registration, standards setting and fitness to practise. It would also have the funding necessary to market itself and develop a programme of public education about the merits of using appropriately regulated practitioners. New complementary therapies could be included when they met the necessary criteria, and the system would also ensure that complementary therapies would be well positioned should statutory regulation be deemed appropriate or desirable in the future.
- 13. This proposal in no sense diminishes the work that the independently chaired groups have done to date. Indeed, such a proposal is only possible because the professions in question have demonstrated their ability and commitment to working collaboratively, and collectively endorse the need for effective regulation. The recommendations in this Report build on this progress by suggesting a model which preserves distinct professional identities, whilst providing robust and cost-effective regulation.

PART ONE

INTRODUCTION

- 14. This Report has been commissioned to explore options for taking forward the Foundation's three year regulation programme aimed at helping designated therapies to achieve effective voluntary regulation. The eleven complementary therapies identified by the Foundation for inclusion in the programme are: aromatherapy, Alexander technique, Bowen therapy, cranio-sacral therapy, healing, homoeopathy, massage therapy, nutritional therapy, naturopathy, reflexology and yoga therapy. Independent working groups exist for each of these therapies, with a view to bringing together the various registering bodies and professional associations with the eventual aim of establishing a single regulatory body for each profession. Funding has been provided by the Foundation to assist groups working towards this end.
- 15. This model of regulation draws heavily on the arrangements in place for statutory health professions, each of which, until relatively recently, has been regulated under the auspices of a single regulatory body, such as the General Medical Council (GMC) and the General Dental Council (GDC). Notably, the first two complementary therapies to be regulated also adopted this form. The General Osteopathic Council (GOsC) was set up in 1993 and the General Chiropractic Council (GCC) was set up in 1994.
- 16. Whilst other industries have seen the development of whole-sector regulation (for example, the creation of OFWAT, OFCOM and the FSA), health care professionals have continued to be predominantly regulated individually until relatively recently. Each profession has accredited its own training schools, maintained its own register, set its own standards, and administered its own fitness to practise mechanism. The main attraction of this system is the extent to which professionals have felt a sense of ownership and control over their performance, conduct and standard setting. Regulatory bodies have also provided the public with a single register and a single body to contact. Complementary practitioners have followed a similar regulatory route, albeit in a voluntary context.
- 17. But health care regulation has undergone dramatic changes in recent years. Professions are now expected to demonstrate accountability far more than in the past. Accusations that professions have been 'soft on their own' have led to significant alterations of the composition and working practices of many of the statutory regulators. One of the most significant changes has been the transition from the notion of 'self-regulation' to 'professionally-led regulation', in which professions work in partnership with the public and other stakeholders in fulfilling their regulatory functions. The consumer voice is represented through the appointment of lay (or 'public') members onto Councils who work alongside professional members, who are increasingly appointed rather than elected.

- 18. Since 2003, the nine UK statutory health care regulators in the UK have also been overseen by a new independent statutory body, the Council for Health Care Regulatory Excellence (CHRE). CHRE defines its mission as being "to protect the public interest, promote best practice and progress regulatory excellence". CHRE's responsibilities are set out in Part II of the National Health Service Reform and Health Care Professions Act 2002. These are to:
- promote the interests of the public and patients in relation to the regulation of health care professions
- promote best practice in the regulation of health care professions
- develop principles for good, professionally-led regulation of health care professions
- promote co-operation between regulators and other organisations.
- 19. CHRE's public protection jurisdiction is accompanied by wide-ranging powers of inspection and review of the regulators. These include a discretion to refer 'unduly lenient' fitness to practise decisions of the regulators to the High Court (2), and a power to seek directions to make a regulator change or amend its rules, where this is felt necessary to protect the public (3). CHRE has the authority to do anything that it feels is necessary or appropriate to carry out its role, including investigating and reporting on how regulators carry out their functions and comparing the performance of different regulators (4). CHRE, working in partnership with the regulators and other stakeholders, is beginning to map out and encourage best practice in many areas of health care regulation.
- 20. Changing expectations of health care regulation have resulted in other structural and governance changes amongst statutory regulators. Most, if not all of the regulators, are updating their statutes by means of 'section 60 Orders' a legislative device which allows changes to health care professions without recourse to primary legislation (5). Changes include giving regulators a full range of fitness to practise sanctions, powers of interim suspension, mechanisms to deal with poor performance and health as well as misconduct, powers to require mandatory CPD and improved complaints processes. Reforms have also been introduced to change the composition of Councils to include stronger lay (public) representation and to allow professions to regulated wider members of their clinical team.
- 21. Significantly, the two most recent Orders regulating health professionals, which set up the Nursing and Midwifery Council (NMC) (6) and the Health Professions Council (HPC) (7), have not, as in the past, created uni-professional regulatory structures. Rather, each of these regulators regulates a group of professions under a single Council. The NMC is responsible for the regulation of nurses, midwives and specialist community public health nurses, and the HPC (which replaced the Council for the Professions Supplementary to Medicine (CPSM)) currently regulates thirteen different health care professions. The individual professions retain significant levels of

autonomy and representation, but share governance structures and common registration, education and fitness to practise processes.

- 22. In public protection terms, the principle advantage of a federal system is that it introduces a greater degree of consistency in how different professions are regulated, whilst recognising the significant degree of the commonality between health professions. To this end, much of the HPC's guidance is common to all of its thirteen professions, with profession-specific guidance set out as necessary. Arguably, in coming under the HPC umbrella, the profile of the thirteen professions it registers has been enhanced, and the public awareness of these professions increased.
- 23. From a financial perspective, the advantage of this type of structure is the economies of scale which can be achieved by registering a larger number of practitioners under an umbrella organisation. In 2004, the NMC regulated approximately 660 000 registrants, and the HPC regulated approximately 156 000 registrants. The relative size of these two regulators allows them to charge a considerably lower annual subscription fee than uni-profession regulators. Whereas HPC registrants pay an annual retention fee of £60, the General Chiropractic Council's registrants (GCC) pay £1000 (8).
- 24. A final advantage of a federal scheme is that it is able to add on new professions as and when they are deemed ready for statutory regulation, without the need for primary legislation, and without the need to reinvent the wheel in terms of accreditation processes, registration processes, standards setting and a complaints mechanism. Regulation of new professions is increasingly decided on a *risk-based approach* whereby occupational groups who present a potential risk to the public and who have reached a certain stage of educational and occupational development ought to be regulated. Some of the newly regulated groups might not previously have been regarded as 'professionals', but this is no longer the determining factor, given that the central purpose of regulation is public protection.
- 25. It is significant that acupuncture and herbal medicine, the two complementary professions deemed by the House of Lords Select Committee to require statutory regulation, are also likely to be regulated by means of a federal model, in the form of the tentatively named 'CAM Council'. After extensive consultation, (9,10) this was felt to be a more appropriate model than creating two small regulatory bodies. It was recognised that separately, these professions would lack the critical mass necessary to be able to fulfil the range of functions expected of a modern regulator (11). Many of the complementary therapies under discussion are as small as, if not smaller, than acupuncture and herbal medicine.
- 26. Health care regulation has also come under the spotlight because of a series of highly publicised regulatory failures. Cases including the Bristol Royal Infirmary, Shipman, Neale, Ayling and Kerr/Haslam have

resulted in a spate of public Inquiries which have been critical of many aspects of health care regulation. A common theme to emerge from these Inquiries has been the need for regulation to be far more accountable, and the need for the public and other stakeholders to be involved in the regulatory process, as well as professionals.

- 27. Although many of the Inquiries have been concerned with the activities of doctors, their ramifications extend beyond medical regulation to health care regulation as a whole. In response to the Shipman Inquiry, the Government has established two major reviews, the findings from which will inform the Minister's response to the Shipman Report. The recommendations arising out of these groups may propose some radical changes to the present system of health care regulation (12, 13). All aspects of regulation are being considered. The remit of these groups (set out in Annex 1 and 2) include: considering the need for revalidation or other mechanisms to demonstrate ongoing fitness for purpose; achieving economies of scale, by, for example, contracting out registration processes; improving mechanisms to ensure consistency and sharing of best regulatory practice and looking at whether to reduce the number of statutory health care regulators.
- 28. It is against this backdrop that the Foundation has commissioned this Report with a view to exploring options for the most effective and sustainable regulatory solution for the voluntary regulation of complementary therapies. Accordingly, this paper will trace the background to recent regulatory developments, explore the advantages and disadvantages of different regulatory models for the therapies under consideration, highlight potential areas of dispute, and make recommendations about how to take this process forward.

PART TWO

ANALYSIS OF ISSUES

1. The Foundation's Regulation Programme

- 29. The Foundation's Regulation Programme, initially funded by the King's Fund, and currently funded by the Department of Health, has facilitated and supported therapy-specific independent working groups across a range of complementary professions (14). The aim of each group is to bring together as many registering bodies, training establishments and professional associations within each therapy as possible, with a view to agreeing shared standards. Each group has been facilitated by an Independent Chair, and has managed to bring around the table the bulk of registering bodies within each profession, ensuring the widest diversity of views as possible.
- 30. The aim of this project is highly ambitious. Taking regulation forward requires skilful negotiation and the willingness to compromise. In the past, each complementary profession has had a multiplicity of professional registers and professional associations, representing different therapeutic traditions and models, applying differing educational standards, with varying levels of quality assurance of students and registered practitioners. Because of the common law freedom to practise, standards of training and practice vary enormously across the sector. This has made it difficult for patients to identify who is and who is not an appropriate practitioner (15). The Foundation is committed to facilitating patients' choice and ensuring that the public is able to access safe and competent practitioners.
- 31. All of the therapies working with the Foundation have come a considerable way in terms of professional development. This has not always been a smooth process. The Foundation's regulation work has flushed out many of the difficulties inherent in professionalisation. Controversial areas include: how to reconcile different traditions within the same therapy; how to resolve regulatory and professional frictions between different groupings; where to pitch educational entry levels to the profession (in particular, determining whether entry to the profession should be restrictive or inclusive); the extent to which public safety should take precedence over public choice; and how to fund regulation. (16)
- 32. The current phase of the Foundation's regulation programme has involved selecting a number of therapies who will receive further support to take regulation forward. The Foundation's initial criteria for participation on this programme required each group to have existing structures in place and to be developing plans for the establishment of a single regulatory body for their profession; to have, or be in the process of recruiting, an independent lay chair; to have or be in the process of recruiting independent lay members; and to have adequate

financial resources and financial controls to ensure sustainability of the development work over the three-year period.

- 33. At the time of selection, none of the groups under consideration met the fourth criterion of long-term financial sustainability. This is highly problematic, since professional regulation is funded through registration fees, and rarely attracts external funding. Unless a profession has a certain critical mass, the costs of regulation per registrant will be untenable. Financial sustainability is essential if regulators are to be able to provide the range of activities necessary to ensure public protection, including public education (requiring effective communication strategies such as an accessible and up-to-date website). The lack of financial sustainability has serious implications for the feasibility of encouraging a separate regulatory body per profession, as has been the original direction of travel.
- 34. At the same time, changes taking place in the wider health care regulatory arena have called into question whether separate regulatory bodies are, in any event, the most efficient and effective way of regulating voluntary complementary therapies. As a charitable body, the Foundation is obliged to maximise its resources to promote best practice in regulation. For this reason, it has commissioned this Report to explore and rank realistic regulatory options.

2. House of Lords Select Committee on Complementary and Alternative Medicine

- 35. The influential report of the House of Lords Select Committee considered arguments for and against further regulation in complementary and alternative medicine (CAM) (17). The Report concluded that further statutory regulation in CAM was unnecessary save for those therapies which constituted a risk of harm in unskilled hands. The only therapies identified as requiring statutory regulation were acupuncture and herbal medicine, although the Report also stated that statutory regulation may also be appropriate eventually for homeopathy (18).
- 36. For the vast majority of CAM therapies, the House of Lords took the view that effective voluntary self-regulation provided an adequate means of protecting the public, a view that was endorsed by the Government (19). The Select Committee accepted that at best, voluntary regulation could provide many of the same safeguards of a statutory scheme in terms of registering members, determining educational standards, accrediting institutions, setting appropriate standards of practice and operating a disciplinary mechanism. The House of Lords Report stressed the need for public education, so that the voluntary body becomes synonymous, in the public's mind, with quality assurance. Accordingly, the bulk of complementary therapies were urged to organise themselves under a single professional body per profession, so that progress could be made on identifying consistent, high professional standards. This was the prompt for the

Foundation's current initiative in funding ongoing developments in voluntary regulation.

37. Since the House of Lords recommendations, which were subsequently accepted by the Government, there have been significant changes in the regulatory landscape. The preference is no longer for multiple, small, single regulators within a given sector, but for larger bodies, capable of injecting consistency and cost-effectiveness. This has a very real bearing on how *voluntary* regulation should move ahead in this area. So far, the professional bodies and associations in the Foundation's programme have worked collaboratively, with the ultimate aim of establishing a single register and single body per profession. The question now is whether public protection can adequately be assured through small, separate registering bodies or whether some other mechanism is required.

3. Changes in the regulatory landscape

- 38. The regulation of complementary therapies cannot be considered in isolation from wider social, political and economic social trends. Four particular areas are relevant. These are: the imperative to reduce regulatory burden, the possible outcome of the Government's CMO and Foster reviews, the extension of regulation to the wider workforce, and the growing preference for composite, federal-style regulators.
- *i.* Reducing the regulatory burden through targeted, proportionate regulation
- 39. Health care regulation must fulfil two distinct objectives increasing public protection without imposing unnecessary burden and expense. The Department of Health is committed to increasing protection for patients, vulnerable adults and children in both health and social care sectors. This has been achieved in several ways, including a series of legislative orders to modernise the existing health care regulators, setting up the Council for Health Care Regulatory Excellence (CHRE) to identify and disseminate good regulatory practice, the creation of the General Social Care Council (GSCC) to regulate social workers, and more recently, looking at ways to implement the recommendations of the Bichard Inquiry, set up in response to the Soham murders.
- 40. At the same time, the Department of Health, like all Government departments, is under continuous pressure to demonstrate costefficiency. To this end, it has sought to reduce the amount of money spent on administration and unnecessary bureaucracy and increase the money spent on frontline NHS services. In its rationalisation of arm's length bodies (the ALB Review (20)), comments were made about the cost efficiencies that could be made within health care regulation. CHRE was expressly tasked with ensuring that the potential for sharing corporate services with and across the regulatory bodies be pursued as part of the CHRE's remit to secure greater consistency between regulatory bodies.

- 41. The political drivers which inform statutory regulation must also be factored into any realistic discussion of regulation in the voluntary health care sector. Regulatory attention should be risk-based, proportionate and targeted where it is most needed to protect the public. The question is what should risk-based, proportionate and targeted regulation look like in relation to the voluntary regulation of complementary therapy? The first point has already been made, namely that the form of regulation should be proportionate to the risks, and in relation to most complementary therapies, the House of Lords did not deem the risk sufficient to require statutory regulation. There is little to suggest that the risk has increased or that that voluntary regulation is no longer appropriate for these therapies. But the question of how voluntary regulation should be configured has yet to be explored.
- 42. Core regulatory functions remain necessary, whether the overarching system is voluntarily or statutorily based. Thus, regulation, even in a voluntary scheme, requires effective registration, education and training, standards setting and fitness to practise processes. These are the areas which the independent groups have been concentrating on. The key to a proportionate regulatory response is *how each of these is implemented*.
- 43. A risk-based approach to voluntary regulation could be applied in several ways. In terms of accreditation of training establishments, it could mean that after initial accreditation, schools should be given the freedom to self-certify unless a serious problem is identified, in which case, regular external visits could be reinstated. In terms of initial registration, more detailed and ongoing scrutiny might be required of any practitioner who has previously been convicted of a serious criminal offence or who has been the subject of another body's disciplinary processes. Similarly, in enforcing CPD requirements, it might be appropriate to dip sample the majority of registrant's CPD portfolios, but to scrutinise more regularly the portfolios of any practitioner whose conduct or competence has been called into question.
- 44. Any voluntary scheme of regulation needs to put safeguards in place which permit members of the public to have confidence in complementary practitioners. One of the reasons that this is difficult is that the majority of complementary practitioners work unsupervised, often in sole private practice. This means that the impetus to work safely and ethically relies solely on the propriety of the individual practitioner.
- 45. Complementary health care lacks the organisational safeguards which have been put in place to assure quality of care within the NHS. Unlike the NHS, there is no overarching system of clinical governance, through which organisations monitor, assure and improve the quality of their services year on year, and make sure that they are safe. NHS

organisations and staff are accountable to numerous regulatory bodies, such as the Healthcare Commission, National Patient Safety Agency and National Clinical Assessment Service. Private health care providers, who are increasingly taking on NHS work, are subject to some, if not all, of these controls. They are also putting mechanisms in place to ensure that health professionals are supervised, managed, appraised, and generally subject to clinical governance.

- 46. The challenge is to create alternative mechanisms for scrutinising complementary practitioners' practice. Some of these will be the responsibility of the regulator. Others will fall within the remit of professional associations. Examples of how this might be done include 'virtual' audit and research networks, mandatory peer review, and requiring all newly registered practitioners to be mentored by a more senior practitioner (this could be accompanied by a requirement that all registrants be willing to supervise newly registered practitioners as a condition of their registration). To facilitate this, supervision and mentoring skills could usefully be added to the list of core competencies which all practitioners could be taught as part of their initial training or guided CPD.
- 47. Complementary practitioners have often taken a deliberate choice *not* to work in the NHS. The purpose of this exercise is not to subject practitioners to regulatory requirements which are unnecessarily burdensome and which merely mirror the controls imposed on practitioners working in the NHS. This would be seen as disproportionate, particularly by the many practitioners who work parttime, and use several different therapies. Rather, the purpose of the exercise is to ensure that patients wishing to use complementary practitioners have sufficient information to make wise choices and have the reassurance of knowing that they are being treated by competent, ethical practitioners.
- *ii. Shipman/CMO/Foster Reviews*
- 48. The three year Inquiry conducted by Dame Janet Smith into the case of GP, Dr. Harold Shipman has prompted an historic review of health care regulation and, in particular, the role and functioning of the General Medical Council (GMC) (21). Dame Janet identified numerous problems in the system of regulation which was in operation at the time, many of which have already been rectified. The recommendations in the Shipman Report have far reaching implications for the regulation of all health care professionals and many of Dame Janet Smith's findings are also relevant to this debate. They include:
- Governance arrangements: the composition of regulatory councils is a key factor in ensuring public confidence. The majority of members of regulatory councils should be appointed not elected. Members should be openly and transparently appointed according to competencies, and not elected because they represent a particular grouping.

- Fitness to practise: those who investigate allegations against practitioners should not also adjudicate in these cases. Standards, criteria and thresholds should be developed to ensure fair and consistent decision-making.
- Independent adjudication: rather than each regulator having its own separate FTP mechanisms, thought should be given to the creation of a single adjudication body, with independent, appointed panellists judging cases across a range of professions. Fitness to practise panel members should be shared across regulators.
- 49. Complementary practitioners need to be aware of the extent to which the Shipman report has prompted the Government to undertake a fullscale review of health care regulation. To help to inform its response to the Shipman recommendations, the Government has set up two parallel reviews to consider the regulation of doctors and the regulation of the non-medical workforce (12, 13). The Chief Medical Officer (CMO), Sir Liam Donaldson, is carrying out the first of these two reviews. His remit (set out in full in Annex 1) is to identify measures to:
 - strengthen procedures for assuring the safety of patients in situations where a doctor's performance or conduct poses a risk to patient safety or the effective functioning of services
 - ensure the operation of an effective system of revalidation
 - modify the role, structure and functions of the General Medical Council (GMC)
- 50. The second review of non-medical professional regulation (headed by Andrew Foster, the Department of Health's Director of Workforce), is considering the regulation of all health care professionals other than doctors (albeit with a strong focus on health professionals working in the NHS). This review (the remit of which is set out in full in Annex 2) will consider the measures needed to:
 - strengthen procedures for ensuring that the performance or conduct of non-medical health professionals and other health care staff does not pose a threat to patient safety or the effective functioning of services, particularly focusing on the effective and fair operation of fitness to practise (FTP) procedures
 - ensure the operation of effective systems of continuing professional development (CPD) and appraisal for non-medical health care staff and make progress towards regular revalidation where this is appropriate
 - ensure the effective regulation of health care staff working in new roles within the health care sector and of other staff in regular contact with patients
 - in the light of the above, it will further consider and recommend any changes needed to the role, structure, functions and number of regulators
- 51. Although the CMO's review is focussed specifically on the General Medical Council, it raises an issue of central importance to all health care professionals, which is whether initial registration should entitle a

person to practise for life, or whether it is necessarily periodically to review a practitioner's fitness to practise throughout his or her professional career. This same question needs to be addressed in relation to complementary practitioners. The debates emerging from these two reviews will inform the Government's thinking on the appropriate form of regulation for the wider health and social work force. This also has implications for the ultimate form of regulation of complementary practitioners.

- 52. Doubtless, the major difficulty of reforming the statutory sector is that any change would involve altering the *existing statutory arrangements* in place for nine separate bodies. Any attempts to change the legislative basis upon which the statutory professions are regulated would be extremely costly and time consuming. Regulators are understandably concerned that any structural changes required of them would need to provide better public protection than the system which already exists.
- 53. In complementary medicine, by way of contrast, the *lack of* a statutory basis and the relative fluidity of regulatory arrangements provides a timely and genuine opportunity to establish an overarching model of regulation which is both responsive to current best practice including forthcoming protections for children and vulnerable adults, compliant with Better Regulation Task Force (BRTF) principles (22) and future-proofed against likely regulatory developments. Complementary therapies are ideally placed to introduce truly innovative regulatory processes which protect the public, and support individual freedom of choice, whilst maintaining change and diversity in complementary therapies.

iii. Regulation of wider workforce

- 54. Regulation of complementary therapies also needs to be seen in the context of the Government's wider plans for modernising regulation (23). A significant aspect of its modernisation agenda is the plan to extend regulation to the wider workforce (24). In the past, regulation has been seen as a privilege, not a right, restricted to 'professions' (25). Now, as discussed, the emphasis on protecting the public is leading the Government to consider mechanisms to regulate the wider health and social care work force *based on assessment of risk*, even though they may not be considered 'professionals'. Regulation, possibly in the form of an occupational register or occupational licensing, has been recommended for health care support workers (possibly under the HPC, or spread amongst a range of existing regulators) and the social care workforce (probably under the General Social Care Council (GSCC)).
- 55. The main rationale for regulation is that these are staff whose work *has a direct impact on patient care*. As stated, these are not groups who necessarily fall into the category of 'professionals'. Rather, the impetus for imposing some form of regulation is public protection. Given that

the relationship between complementary practitioners and their patients may also be physically and emotionally invasive, and often takes place in an unsupervised, unmanaged environment, regulatory developments in the wider health and social care workforce are also relevant to this debate.

- *iv.* Composite or Federal-style regulators
- 56. The creation of the NMC and HPC (like the Council for Professions Supplementary to Medicine (CPSM) before it) represent an alternative to the dominant 'Medical Act' model of a single regulator per profession. The HPC, currently regulates thirteen professions, with many more aspirant professions waiting to be regulated. The HPC provides an exemplar of the sort of regulatory structure which could be put in place for complementary therapies. Within the HPC, each of the thirteen professions is represented on the Council and each retains a strong, professional identity. The individual professions continue to have the predominant say over the setting of educational standards and the standards of proficiency required of that profession. Professional associations retain a key role in the advancement and promotion of the professions, the dissemination of research findings and the discussion of political and professional developments.
- 57. It is understandable that many complementary practitioners might still see a single regulatory body as the pinnacle of regulatory achievement. The regulation of osteopaths and chiropractors may have bolstered the expectation that this would be the ultimate regulatory route for other therapies. But much has happened in the intervening decade since these statutory bodies were formed, and the ongoing viability of the smaller, separate statutory Councils will be considered as part of the far-reaching Foster review.

4. Move away from self-regulation to professionally-led regulation

58. In the past, regulation in relation to complementary health care has referred either to 'statutory self-regulation' (often called SSR) or 'voluntary self-regulation' (often called VSR). It is worth restating the difference between statutory and voluntary regulation, not least of all because some of the professions under consideration may have considered moving towards statutory regulation. Ideally, an effective voluntary self-regulating scheme will share many of the features of professionally-led statutory regulation, namely: a single register of practitioners per profession; externally accredited education and training; codes of ethics; and FTP processes/complaints mechanisms. The key difference in terms of public protection is that a voluntary system lacks statutory protection of title. What this means is that people who are not on a register may nonetheless practise a regulated therapy or use a particular title without that constituting a criminal offence.

- 59. Regulation is a dynamic process. The terms statutory self-regulation and voluntary self-regulation fail to reflect important shifts in regulation which have taken place in recent years. As stated, the preferred term now used in the statutory health care sector is 'professionally-led regulation'. This indicates a shift away from unassailable professional autonomy and control towards an accountability model in which professions work in partnership with other stakeholders who have a legitimate interest in the way a profession is regulated. The General Social Care Council (GSCC), who operate the newest statutory register, take this one step further by having a lay (public) majority on their governing Council.
- 60. Professionally-led statutory regulation creates a protected title, and in a few cases, protected functions, which are limited to professionals on a statutory register. Whereas education processes, standard setting and fitness to practise (FTP) arrangements continue to rely on substantial professional input, lay/public involvement is embedded in all aspects of the regulatory scheme. It is this aspect of professionally-led regulation that characterises the substantive shift away from self-regulation, in which the profession is the sole arbiter of the standards it sets for itself, who it registers, and who it de-registers. The move towards stakeholder regulation is not merely cosmetic, but reflects societal shifts and consumer expectations. Good regulation and good governance require there to be formalised mechanisms in place through which those with a legitimate interest in the regulation of a professions can make a meaningful contribution to the regulatory process.
- 61. Any proposals for the regulation for complementary therapy need to consider how much bearing stakeholder regulation should have on voluntary regulation. The insistence, by the Foundation, that each group has a lay chair and a substantial lay membership recognises the extent to which professional regulation is expected to draw on a wider base of expertise than in the past. Far from a loss of professional autonomy, partnership involvement *enhances* the regulatory process, by demonstrating a commitment to accountability and good governance which are at the basis of public confidence.
- 62. The next section considers which features of best practice in statutory professionally-led regulation need to be accommodated within a regulatory scheme for voluntarily regulated professions.

5. Best practice in professionally-led regulation

63. Whereas best practice is the subject of considerable debate in the statutory sector, there has been very little discussion as to what might constitute best practice in voluntary regulation. The features of voluntary self-regulation set out by Mills and Budd (cited by the House of Lords Select Committee and reprinted at Annex 3) need to be revisited in the light of more recent regulatory developments.

- 64. It has often been argued that the only difference between statutory and voluntary is that statutory regulation provides statutory protection of title. Beyond that, since both systems are designed to protect the public, an effective system of voluntary regulation could be expected to have largely similar mechanisms in terms of registrations processes, education and training requirements, standards setting and mechanisms for when things go wrong.
- 65. A significant part of CHRE's work has been to build on the collaborative work of the regulators to determine best practice in regulation and make sure that regulators are adopting this (subject to their individual legislative schemes). Currently, features of best practice in professionally-led regulation might include:
- compliance with the Better Regulation Task Force's (BRTF) five principles of transparency, accountability, targeting, consistency and proportionality
- clear separation of public protection functions (the role of the regulator) from promotion of the profession (the role of professional associations)
- small, strategic Councils with a significant lay/public presence, if not a lay majority and/or lay Chair, and lay representation on most, if not all, core committees
- effective systems of corporate governance, including independent appointment of Council members and panel members against clear, transparent criteria, and periodic assessment against those criteria
- three/five year business and corporate plans to ensure an infrastructure is in place and adequate funding is available to develop and implement Council policy
- a commitment to partnership working
- a risk register or other risk assessment strategy
- registration processes to include compliance with forthcoming Bichard requirements for enhanced CRB checks to ensure that registrants are safe to work with children and vulnerable adults (26)
- a publicly available, up-to-date register of individual practitioners (not a register of registering organisations or training schools)
- the register denoting specialist qualifications (if applicable) and historical fitness to practise information (i.e. whether the practitioner is subject to a disciplinary sanction, or has been in the past)
- independent accreditation of educational processes against identified competencies, as well as processes for ongoing quality improvement within training schools
- a published scope of practice against which performance can be monitored (including specialist practice, if appropriate)
- effective continuing professional development (CPD), linked to ongoing registration, and/or consideration of periodic revalidation or assurance of ongoing fitness for purpose
- recognition of the need to promote a culture of openness and the importance of reporting poor practice of other practitioners
- training and standards guidance on boundary maintenance (including how to avoid physical, emotional, sexual and/or financial boundary violations)

- robust, fair, and transparent fitness to practise (FTP) processes, with clear standards, thresholds and criteria, and separation of investigation and adjudication functions (so that the officers/Council members who investigate a complaint do not also adjudicate on it)
- mechanisms for considering not only conduct cases, but also health cases (allegations that a practitioner is unfit to practise by way of poor physical or mental health) and performance cases (allegations that a practitioner's performance has fallen below an acceptable level). The trend is towards considering all aspects fitness to practise of a case holistically, through a single FTP committee
- independent (i.e. non-Council) FTP panel members appointed against competencies, and required to undergo regular training and assessment
- indicative sanctions guidance and restoration guidance to inform FTP panels about the Council's policy
- compliance with best practice in ethnicity and diversity monitoring and training
- 66. Each of these features is aimed at ensuring public protection. Most if not all of them should be present in a voluntary structure. So are there any meaningful differences between voluntary and statutory schemes? Arguably, the key difference between a statutory scheme and a voluntary scheme is that a voluntary scheme is just that. *The system is voluntary* practitioners do not have to be registered, even though there are demonstrable benefits to their patients and themselves to be registered. Critically, there is no statutory requirement for these practitioners to be regulated, and thus no legal sanction for practising that profession without being registered.
- 67. Historically, the common law freedom to practise which has characterised regulation of this sector has reflected a desire to allow members of the public freedom of choice in who they choose to treat them. Few legal controls are placed on the ability to practise, and the main route for redress, if any thing goes wrong is through the courts. Market forces, it is argued, offer a form of protection, in that unskilled or poor practitioners will soon lose custom. This is wholly inadequate from a public protection point of view, as it means that patients may be harmed in the interim, and will have nowhere to complain to, and no mechanism for holding the practitioner accountable, other than initiating legal proceedings (15).
- 68. Regulatory regimes elsewhere are not so liberal (27). In many other jurisdictions, the practice of complementary therapy is either limited to registered health care professionals, or subject to a form of licensing. As the use and integration of complementary therapies continues to grow in the UK, the justification for therapies remaining substantially unregulated sits increasingly at odds with the regulation of other practitioners, justified on the basis of public protection and perception of risk.

- 69. One reason why it has been felt impractical or inappropriate to regulate these therapies is that many of the therapies under discussion are used by people as part of a self-care regime. Examples include the significant use of over-the-counter products such as aromatherapy oils and food supplements, and the personal practice of massage as a tool for recreation and relaxation. Self-care is an important aspect of health and healing which should be promoted as part of a preventative health care strategy. The challenge is to regulate those who hold themselves out as health professionals (i.e. those who create the expectation of a therapeutic relationship, whether or not they charge for treatment (28)) whilst permitting the use of therapies as part of selfcare. This makes regulation more challenging, but certainly not impossible.
- 70. The key to devising the most appropriate regulatory structure of voluntary regulation is to find a model which strikes a balance between light touch regulation, as far as is possible, maximising patient choice and supporting practitioners' freedom to practise, whilst simultaneously providing *advantages to registrants* which do not exist within current voluntary structures. The success of any regulatory proposals will be in the extent to which they facilitate safe and effective practice by competent, qualified complementary therapy professionals and attract widespread professional support.
- 71. Within the statutory arena, health professions have strong positive and negative incentives to become registered. In positive terms, being statutory regulated allows (although does not guarantee) employment in the NHS or private health care. The negative incentive is that to practise without being duly registered constitutes a criminal offence which can result in prosecution. *Neither of these incentives pertain to voluntarily regulated professionals.*
- 72. Accordingly, the next section considers the advantages and disadvantages of the realistic regulatory options available to complementary practitioners. The three options put forward are: preserving the status quo, the pursuit of statutory regulation, and a federal structure for regulating voluntary complementary therapies.

PART THREE

REGULATORY OPTIONS

a. Maintaining the status quo

73. This option would allow therapies to continue to professionalise at their own pace. This system is based on market forces, and as such, will continue to be characterised by multiple training and registering bodies, all purporting to offer patients guarantees of quality service provision. Although the therapies under discussion have so far managed to bring together many of the professional groups, some bodies resist moves towards a single body. In addition to the numerous professional registers, some of which accredit graduates of private training establishments, several multi-professional bodies claim to act as overarching regulators, although none appears to have a publicly available register, robust fitness to practise (FTP) system or publicly available record of de-registered practitioners. Amongst the therapies under discussion, some are practised by nurses and other health care professionals. There is some, limited provision within the NHS, although arrangements tend to be on an ad hoc basis and would-be commissioners are deterred by the absence of a single, reliable point of contact.

Advantages of status quo

- allows each profession to develop at its own organic pace, recognising that some professions have been moving towards regulation for a longer period of time than others
- allows different professional bodies to decide what structures they want in place and what entry standards they are prepared to accept
- allows diversity and is maximally inclusive (although the present process may nonetheless have failed to capture certain groups of practitioners who resist formal regulation)
- allows a profession to determine what its scope of practice should entail
- allows practitioners to choose from a wide variety of training courses and registering bodies to suit their purse, desired length of training and professional orientation
- allows practitioners to belong to several registering bodies to maximise their advertising potential and exposure to potential clients
- allows practitioners to have a core professional qualification, but to practise a range of other therapies, with or without registration in those additional areas
- tacitly acknowledges and accepts that it will never be possible to persuade all practitioners to join a register, but provides mechanisms for those who *do* wish to be formally regulated

Disadvantages of status quo

- the therapies under discussion are amongst the most widely used complementary therapies, which means that people need good advice about appropriately trained practitioners
- it is hard to choose between practitioners when so many diverse qualifications and registers exist for each therapy
- diversity allows for unacceptable variation in training standards, with some courses and qualifications available after days, weeks or months
- market forces are an unsatisfactory way of ensuring public protection because practitioners may work without insurance or any other accountability mechanisms, meaning that patients may have no redress if something goes wrong
- the absence of any form of mandatory licensing means that practitioners who have not even been subject to a criminal records (CRB) check are free to work with vulnerable adults and children, and often do so in an unsupervised setting
- the existence of multiple registers means that a practitioner who is subject to a disciplinary sanction from one registering body may simply register with another registering body and continue to practise (or indeed, continue to practise with no registration and no insurance) and there is no mechanism for a patient to trace the practitioner's disciplinary record
- tenets of good professional practice are readily identifiable and should be consistently enforced across the health care sector
- allowing therapies to develop in professional isolation means they do not have the benefit of adopting existing best practice and are likely to reinvent the wheel
- given the critical mass of some of the therapies under discussion (with some of the professions under discussion having hundreds rather than thousands of practitioners), single regulatory bodies are not financially viable

b. Statutory regulation

74. Statutory regulation has historically been seen as the hallmark of a mature profession. In the health care arena, statutory regulation has required a profession to demonstrate that it possesses a discrete, evidence-based body of knowledge. Osteopathy and chiropractic achieved statutory regulation in 1993 and 1994. The House of Lords encouraged statutory regulation for acupuncture and herbal medicine, mentioning the possibility of statutory regulation for homeopathy at Recently, statutory regulation has been some future date. recommended for the wider health and social care workforce, although the form that this regulation might take is still uncertain. Statutory regulation of the existing nine health professions is in a state of considerable flux, whilst the Government reviews the role, functions and structures of existing bodies in the light of highly publicised regulatory and service failures and with reference to current and future workforce needs.

Advantages of statutory regulation

- protection of title, backed up by criminal sanction
- provides appropriate mechanisms to ensure standardisation of training and practice
- may become appropriate or necessary if the risks of the therapy cannot be adequately managed in any other way
- places complementary therapies on an equal footing with statutory regulated professions which may be desirable to some therapies (particularly those therapies which are popular with, and practised by, conventionally trained health care practitioners)
- may be seen by some as providing a profession with a certain status
- specifically, statutory regulation would provide parity with other ostensibly complementary therapies which are already statutorily regulated, such as arts therapy, which is regulated by the HPC

Disadvantages of statutory regulation

- statutory regulation is about public protection it is not about status. Statutory regulation is a privilege, not a right.
- Statutory regulation will not be forthcoming merely because a profession decides that it wishes to pursue this route. A profession will not be considered for statutory regulation unless the government feels this is appropriate
- BRTF states need for proportionality. The House of Lords Report considered statutory regulation to be unnecessary for the bulk of CAM therapies. Statutory regulation will not be forthcoming if adequate public protection can be assured through less burdensome means
- statutory regulation is in a state of flux any complementary profession seeking statutory regulation at the present time is more likely than not to find itself part of a federal regulatory structure
- statutory professions need to be sufficiently financially robust to provide the range of services required of a modern health care regulator
- statutory regulation has, in the past, required complementary therapies to demonstrate an evidence base which may not yet exist (or may not exist in an 'acceptable' form) for some of the professions under discussion (29)
- a statutory scheme is necessarily more expensive to set up than a voluntary scheme. Statutory requirements include the drafting of rules, the need to set up statutory committees and a duty to produce various annual reports. Statutory bodies may, in the future, be directly accountable to Parliament. In practical terms this means that unless regulation captures hundreds of thousands or practitioners, registration costs are likely to be greater in a statutory scheme than a voluntary scheme
- even if a profession becomes statutorily regulated, this is no guarantee of increased referrals from orthodox practitioners, nor is it a guarantee of state-provided provision within the NHS

c. A composite, federal-style voluntary organisation

75. This form of regulation envisages the creation of a new single voluntary regulatory body of complementary therapies. The form of regulation proposed is a federal structure, akin to the Health Professions Council, in which a single Council oversees a number of separate professions, each of which is instrumental in setting its own education and practice standards and represented in discussion of generic professional issues. This model could accommodate new therapies as they professionally develop.

Advantages of federal-style regulation

- a federal body would be able to deliver a common, consistent framework for regulation in step with health care regulatory policy and would ensure equal protection across the range of most widely used therapies
- the branding potential for a single federal body would quickly allow it to assume public recognition and market dominance. By establishing a single body, the public could be educated to recognise this body as a mark of quality control (cf. ABTA, ATOL, Corgi registration)
- a federal body would allow economies of scale compared to eleven single regulatory bodies in terms of a single register, a single registration process, a single accreditation system based on NOS or other appropriate competencies, common standards and a single fitness to practise (FTP) system to hear complaints against practitioners. The result of these economies would result in better public protection for consumers and reduced registration fees for individual registrants
- public protection would be further enhanced because registration with this body could be compliant with Bichard requirements for safeguarding children and vulnerable adults, through voluntary compliance with a system of enhanced CRB checks, providing reassurance to clients and further leverage for entrance into the NHS
- because it would have a single register, a federal system would ensure automatic removal from the register of any practitioner who is erased because of impaired fitness to practise
- creating a single structure would facilitate the creation of a single independent accreditation board. This again would lead to economies of scale and greater consistency between therapies. This is particularly relevant in complementary health where practitioner commonly practise more than one therapy
- a single accreditation board could take the lead in working with professional associations to create core, cross-cutting professional modules in areas central to all therapies, including ethics, law and communication skills, therapeutic relationships, cross-cultural dimensions of healing, audit and research skills, supervision and mentoring skills, IT skills and small business skills
- deriving from its externally accredited education and training, a respected voluntary regulation body would enable strategic partnerships to be made with appropriate research and development

bodies, and would be a credible liaison point for NHS Research and development (R&D). This, in turn, would increase the evidence base for these therapies, feeding back into education and training and higher practice standards

- a composite, federal style regulator would have greater negotiating power than multiple, single bodies in relationships with: private health insurers who wish to offer complementary practitioner to their customers; NHS providers (in NHS and private facilities); and indemnity insurance companies
- in terms of private health insurers (such as BUPA), registration with a credible federal style regulator could, in time, obviate the need for private patients to be required to access a practitioner by means of a GP acting as a gatekeeper
- potentially, recognition by existing statutory health regulators that registrants of a federal voluntary body can be the subject of referrals and be seen as accountable for their own professional actions
- potentially, acceptance by existing statutory health regulators of the federal regulator's educational qualifications and CPD as the appropriate benchmark for practice of a complementary therapy by their own registrants, i.e. the federal body to provide the only acceptable recognised educational benchmark for nurses wishing to practise reflexology or aromatherapy
- a federal system would be better able to cater for practitioners who practise several therapies because practitioners would only need to pay for registration once, but could have their name entered on several sections of the register provided they had the appropriate qualifications
- albeit a voluntary organisation, a sufficiently respected federal style regulator would become the obvious point of contact in terms of EU negotiations
- a federal style body is more likely to be financially sustainable beyond the period of the Foundation's funding

Disadvantages of federal style regulation

- unless such a body attracted the full support of professional membership, the status quo would be replicated, because there would be more than one professional register per therapy and more than one body asserting its legitimacy to speak as the authoritative regulatory voice
- practitioners would have to find ways of working collaboratively with different professions and identify areas which require a pan-professional approach
- representation of professionals and funding would need to take account of the relative size of different constituent professions
- any structure would need to be designed in such a way as to be able to accommodate new professions as and when they become ready to join the scheme
- provisions might need to be created for groupings of complementary therapies at some point in the future

- accusations from existing multi-professional bodies that they already offer federal-style registration. Although such bodies fail to deliver best practice in regulation to the specifications set out above, their ongoing existence in the market place could serve to confuse the public and other would be strategic partners
- 76. For the reasons set out above, a single federal structure appears to have more advantages and fewer disadvantages than other regulatory options and should therefore be seriously considered as the way forward. The rationale for this approach is explored in the next section, through posing a series of likely questions and providing possible answers.

A FEDERAL STRUCTURE: SOME LIKELY QUESTIONS AND ANSWERS

- Q1. Currently, the Foundation is supporting individual bodies for each profession. Is the proposal for a federal system shifting the goalposts, and if so, why?
- A1. Developments in the regulation of complementary therapies cannot ignore developments in the wider regulatory arena. Outside health care, there has been a major shift towards whole sector regulation. Within health care, there have been significant developments since the House of Lords' Report in 2000, including the need to reduce impact of regulation on the economy, regulatory failures, including Shipman, leading to a review of the entire regulatory field, and preliminary moves to regulate the wider health and social care workforce. During the same period, the BRTF has set out principles of good practice in regulation which have been widely adopted in health and other sectors. Taking these developments into account, the proposal for a single federal system builds on current best practice and is intended to ensure that all complementary therapies are optimally regulated.

Q2. Does this mean the work that profession-specific groups have done to date has been a waste of time?

A2. On the contrary. The work done by the groups to get profession specific 'house in order' has not been wasted and is an essential precursor to moving into a more federal approach. Each individual profession will continue to have the key say in the standards and education required of its registrants. It wouldn't have been possible to contemplate working across professional boundaries whilst professions remained individually disunited. But as professions have moved along this process, there has been growing recognition that each might be 'reinventing the wheel' and that there would be benefits in collaborative ways of working.

Q3. How would a single regulatory structure be funded and who would 'own' it?

A3. As in the statutory sector, a single, federal regulatory structure would be funded primarily through initial registration and annual subscription fees. A federal structure allows for economies of scale which means that the registration fees would hopefully be considerably lower than would be the case with a series of separate regulatory bodies. Next stages would need to involve scoping likely set-up and development costs, and considering whether any external funding could be sought. A body would be owned by the professions it regulated. This is why this process needs to be the subject of full and proper consultation with complementary practitioners and other relevant stakeholders.

Q4. Will the registration fees to belong to a federal body be as low as the NMC and HPC?

A4. The fees required to fund a regulatory body depend, critically, on the number of registrants. Nurses, for example, pay a £60 annual retention fee because there are around 660 000 registered nurses, midwives and specialist community public health nurses on the NMC register. It's impossible to predict how many complementary practitioners would be eligible to join the scheme, but the more that are registered as part of a federal scheme, the lower the registration fees will be. That said, fee structures need to be set at a realistic level if the scheme is to deliver adequate public protection. Enhanced criminal records checks should be factored into the cost of registration, because these provide a baseline assurance that registrants are fit to work with vulnerable adults and children and will provide considerable reassurance to the public.

Q5. If registrants fund regulation, shouldn't it be up to practitioners to decide what form regulation should take?

A5. Because this is voluntary regulation, professionals have to buy in to the proposal. A new voluntary system can't be imposed on practitioners, because they will have the responsibility of setting up and running the scheme. A system won't be successful unless professionals support it. But this doesn't mean that they are the only people who have a view about the form that regulation should take. Regulation, whether it is statutory or voluntary, is about protecting the public. This means that regulatory proposals need to be workable. Examples from elsewhere show that bodies which lack critical mass cannot provide optimal levels of public protection. The only sensible way ahead is for complementary professions to join forces and capitalise on their collective strength and capacity.

Q6. Studies repeatedly show complementary therapies to be less harmful than conventional medicine. Doesn't this imply that complementary practitioners can be less tightly regulated?

A6. There are harms involved in all therapeutic interventions, be they conventional or complementary. As well as physical harm, healing relationships also have the capacity to cause emotional harm. The unsupervised context in which many complementary practitioners work mean that certain risks of harm, such as failing to maintain appropriate boundaries, may be more prevalent. The public is entitled to expected similar levels of protection when anyone holds themselves out as a health care practitioner. They should reasonably expect to be able to find a practitioner on a publicly available register, indicating whether they have any areas of expertise and whether they have ever been the subject of disciplinary proceedings. They should be able to expect the practitioner to be properly trained, to work within a code of ethics, to be covered by indemnity insurance, and to be able to be de-registered if they are deemed not fit to practise.

Q7. Will larger professions end up subsidising smaller professions in a federal structure?

A7. Precise funding arrangements would need to be carefully worked through. If funding were on a per capita basis, then larger therapies would, in a sense, be providing more resources than smaller therapies, but the cost to individual registrants would be the consistent. It would be difficult to envisage a workable system where registration fees were proportionate to the size of the profession, especially as this would fluctuate year on year. Costs would, of course, diminish as more practitioners recognise the benefits of becoming registered.

Q8. None of these therapies has ever had a single register of practitioners before. Who'll be eligible to join this register?

A8. Undoubtedly, hard choices will have to be made about whether the initial register should require practitioners to demonstrate a particular standard *before* they can be admitted (e.g. through an exam or other form of assessment, such as a Professional Portfolio), whether practitioners can be admitted *provisionally* with a view to acquiring additional competencies within a given timescale (e.g. through guided first year CPD), or whether some other mechanism, such as a grand-parenting clause, should be introduced to allow onto the register practitioners who have been practising safely for a period of years. The key is proportionality. If the initial register sets its entry level too low, the public will continue to be exposed to potentially unsafe practitioners. If it sets it too high, too few people will be eligible to register, and unregistered practitioners are likely to carry on practising anyway, which will also involve a risk.

Q9. Some practitioners don't charge for their services. Will they be expected to pay the same as practitioners who do?

A9. Whether practitioners choose to charge for their therapy is entirely up to them. Many practitioners operate sliding scales, and others routinely provide services for free in voluntary settings. The point is that the potential risk to patients is the same whether a practitioner charges or doesn't charge. Regulatory bodies are there to protect patients. All registrants who enter into therapeutic relationships with patients have ethical and legal responsibilities, whether they charge for their services or not. They can't 'contract out' of systems to protect patients if things go wrong. This is a scheme to regulate trained, appropriately qualified practitioners. Most of these practitioners will, presumably, have had to pay to study on their professional course. This scheme would not seek to outlaw religious healing or unpaid traditional healing practices, it would simply help members of the public to identify properly trained and accredited complementary practitioners.

Q10. If I practise one of the eleven therapies and refuse to join this scheme, will I be barred from working?

A10. This will remain a voluntary scheme. You cannot be forced to join a register against your will, nor will your continuing to practise your therapy become a criminal offence. However, the advantages of belonging to this scheme will be significant. The mere fact that you are practising does not mean that you will be automatically eligible for registration. You will need to demonstrate that you are able to satisfy certain competencies. This may require supplementing your knowledge with additional training and/or CPD.

Q11. Can a federal style structure accommodate different size therapies?

A11. One of the advantages of a federal style structure is that it allows for considerable variation across the professions it regulates. Although the federal body sets outs certain core requirements, the size of different professions may vary considerably. Nonetheless, a therapy needs to have a certain critical mass before it is capable of being regulated. A 'split off' therapy with a handful of practitioners is unlikely to have a core body of knowledge, backed up by evidence, to differentiate it from other modalities.

Q12. Won't professions lose their professional identity in a federal style structure?

A12. Using the HPC as a comparator, there is no reason to think that professions will lose their identity as part of a federal structure. If anything, the position of the individual professions has been enhanced through the process. Individual professions maintain significant professional autonomy within a federal structure. Additionally, the role of professional associations will be enhanced, and will continue to provide a vehicle for promoting strong professional identities, and mechanisms for professional research and development.

Q13. Won't bringing all of the training schools into a federal structure wipe out their distinct qualities and therapeutic orientation?

A13. No. The purpose of a core professional standards and external accreditation processes is to make sure that all registered practitioners are safe to practise within an accepted scope of practice. Beyond this minimum assurance, schools would continue to be able to teach different orientations and styles, in much the same way as different medical schools, all registered and accredited under the auspices of the GMC, offer wide variation in their style and teaching methods. An advantage of a federal structure is that good practice can be shared easily across other professions.

Q14. Can a federal structure accommodate therapies at differing stages of organisational development?

A14. Certain minimum criteria would need to be satisfied before a body will be eligible to join a federal structure. Detailed negotiations will need to

take place to decide how advanced a profession needs to be before it could be accommodated within a single regulatory structure. Part of the benefit of a federal structure is to ensure patients that all professions represented have achieved certain standards in relation to education and training, fitness to be admitted onto, and stay on the professional register, and disciplinary processes if things go wrong.

Q15. Will professions who are not part of this process be materially disadvantaged?

A15. The aim of an overarching federal structure is that it will be able to take on more professions when they have reached the necessary standards. Because this is a voluntary scheme, professions, or individual practitioners cannot be forced to join, but it is expected that within a short period of time, the reasons for doing so would be more compelling than attempting to practise without this highly visible and publicly recognisable registration. In time, it is hoped that many more therapies would work towards inclusion on such a register.

Q16. Who will recognise a federal VSR body, and how much legitimacy will it have?

A16. To maximise its effectiveness, a federal body would need to be well marketed and accompanied by a programme of public education, so that consumers know about the body and understand what it does. Legitimacy will come from the ability of such a body to demonstrate its commitment to public protection through high standards, through its ability to negotiate with the NHS, to negotiate with insurers for preferential rates, to negotiate with private health providers and potentially, to persuade the statutory regulators to refer to practitioners regulated by such a structure. Properly managed, a single federal structure would, optimally, become synonymous with quality assurance in complementary therapy. The proposed structure should provide the Department of Health with reassurance that this sector has its house in order. If practitioners put effective structures in place of their own accord, this will reduce the likelihood of external mechanisms being imposed on them.

Q17. Will a single federal style body be able to accommodate further CAM therapies in the future?

A17. Theoretically, a federal structure can accommodate any number of new therapies. But any profession wishing to join the regulatory body would need to come up to certain agreed minimum standards. These might include: a minimum number of professionals per profession, independent accreditation of education establishments based on National Occupational Standards or some other competence based model, and commitment to abide by codes of ethics, and agree to be bound by the regulator's fitness to practise processes.

Q18. What role will professional associations play if a single federal structure is created?

A18. Inevitably, the role of professional associations will change if a new, whole sector federal style regulator is created. Voluntary bodies have commonly taken on the role of regulating and representing But these are two quite separate roles, and public practitioners. protection is better served by separating these functions. Professional associations would continue to have a strong and vital role if a federal regulatory body is set up. Their roles would include: promoting professional development, including feeding into standards setting and making CPD recommendations, supporting the creation of specialisms, where appropriate, negotiating bulk provision of insurance cover and negotiating with health care providers and other stakeholders. Professional associations would also be a key player in negotiating standards within and across the EU. For all of the reasons that this Report suggests a federal approach to regulation, professional associations may also, in turn, find that they have a much stronger negotiating voice if they too join forces to become a single, highly visible entity.

Q19. How would a new federal structure differ from existing multidisciplinary professional organisations?

If this single federal style regulator is to have the credibility it requires, it A19. must capture the majority of professionals operating in any given profession. The success of such a structure is that its register, and its *register alone*, would becomes synonymous with the highest standards of professional competence. The single federal style regulator would be the authoritative voice of complementary professions. Significantly, it would hold the one and only overarching register for the professions it regulated, updated in real time, showing practitioners who are qualified, and those who have been subject to complaints or disciplinary hearings. The mere fact that several different bodies have, up until now, put themselves forward as maintaining the definitive register demonstrates the importance of this body being a single, unifying entity. What would mark this structure out is its adherence to processes of accreditation, educational standards and ethical requirements no less rigorous than in the statutory sector, but tailored, specifically to the nuances of complementary practice. If this proposal is to be adopted, then clearly, multi-professional bodies will need to be consulted, and their experience in this field given due weight. Optimally, all registering organisations would seek to come within a single federal structure.

Q20. Is there a maximum number of therapies that such a structure could regulate?

A20. Theoretically, there is no maximum number, and the larger the body, the more influence it will be able to wield. By way of comparison, the HPC currently regulates thirteen professions, and is considering

applications from numerous aspirant professions. Each aspirant professions must satisfy the Council of its readiness to join the statutory scheme. In terms of processes, the HPC could continue to register many more professions. In governance terms, regulators need to match professional members with corresponding non-professional or lay members. To avoid the size of the governing Council becoming too unwieldy, it may be necessary in any federal structure to group therapies within certain categories, e.g. body work therapies, energy based therapies, product based therapies.

Q21. A federal structure sounds almost as burdensome as statutory regulation. Why shouldn't we just pursue statutory regulation?

- A21. It's true that many of the requirements for effective voluntary regulation are as onerous as statutory professions. But it's through high standards that such a body will achieve credibility. Current Government policy is for the potential rationalisation and harmonisation of existing statutory bodies. This is not the time to be thinking about creating new statutory bodies if this has been found to be unnecessary by the House of Lords Select Committee in terms of public protection. But an advantage of being regulated to such high standards through a voluntary system is that transferable mechanisms will already be in place if there is a change in Government policy.
- Q22. Complementary practitioners hold different therapeutic belief systems and have different therapeutic relationships with patients to doctors. Rather than replicating a 'Medical Act' style form of regulation, isn't it possible to devise a regulatory model which reflects what's special about complementary therapy?
- A22. Regulation in the form described is not unique to medicine. The same model underpins all professional regulation across sectors. Although there are fundamental differences, there are also fundamental similarities in the values and ethos underpinning healing professions, making this model transferable. The challenge will be to imbue this model with values central to complementary practice. This can be achieved through the prominence given in education and training to the therapeutic relationship, and by promoting supervision and mentorship more congruent with apprentice models found in traditional therapies. By developing core modules, this federal body will be a forerunner of regulatory excellence and could, itself, create best practice from which statutory regulation could learn lessons.

Q23. What would happen if the eleven therapies don't want to be part of such a federal structure?

A23. The essence of any voluntary structure is that practitioners can choose to work outside it. The history of complementary medicine is littered with individuals who have been dissatisfied with existing structures and have set up their own body and own register – a situation which has led to the unhelpful levels of fragmentation and splitting which has

hindered CAM development in the past. But the freedom to remain able to treat patients comes with certain professional responsibilities. This may, in the future depend on complementary practitioners being able to persuade the Government that complementary medicine is capable of regulating itself and putting adequate safeguards in place to avoid the need for external controls.

Q.24 Some groups have only just managed to bring a single profession together. Won't this scheme take years to develop?

A.24 Creating a federal body is a significant task, which will probably take years rather than months to create. Realistically, some professions will need this length of time to develop single profession unity. The benefit of this model is that it allows less developed professions to leap-frog in developmental terms and to learn from those therapies who have been working towards regulation for longer. Working towards a single model will require patience, skilled negotiation and compromise. This will not be an easy task, but the outcome will be a unique regulatory model which will provide the highest level of public protection and should provide complementary therapists in the UK with credibility both nationally and internationally, now and in the future.
PART FOUR

CONCLUSIONS

- 77. This Report has explored the current regulatory status of complementary therapies in the voluntary sector, options for regulation, and the arguments in favour of a single, federal regulatory body. The parameters of the debate have shifted considerably since the House of Lords Report in 2000. Whereas best practice in voluntary regulation was relatively uncharted at that point, developments in the statutory sector, and the work of CHRE, have made it easier to identify how regulation can best protect the public whilst not unduly restricting the freedom of practitioners.
- 78. The current lack of statutory controls over complementary therapy provides a timely and significant opportunity to introduce best practice in a form that is congruent with the underlying philosophies of complementary practitioners. The challenge is to accommodate within a federal style model the patient-centred, holistic beliefs underpinning complementary therapy. The proposed mechanism is ambitious. Professions will have to be prepared to negotiate and compromise to find acceptable solutions. Proceeding down this route will require widespread consultation involving all interested parties.
- 79. Practitioners may feel that the federal model proposed is unnecessarily burdensome, and too much like existing statutory models. But the high levels of public protection enshrined in this model, and the legitimacy that can be achieved, will be its ultimate strength. This model would also allow complementary practitioners to make the transition to statutory regulation, should this be desired by them or demanded of them at any time in the future, and provides a framework within which a research base can be enhanced to further improve credibility and improve patient care. As complementary therapy becomes an accepted and integrated part of health care, the need for effective regulation is paramount. Public protection does, indeed, come at a price. But the reward is a model which places complementary practitioners at the forefront of regulatory excellence.

GLOSSARY

ABTA - The Association of British Travel Agents. This is a voluntary organisation operating a Code of Conduct and complaints mechanism.

ATOL - ATOL is a protection scheme for flights and air holidays, managed by the Civil Aviation Authority (CAA). Most firms who sell air travel in the UK are required by law to hold a licence called an "ATOL". ATOL protects consumers from losing money or being stranded abroad when a tour operator goes out of business. All licensed firms have to lodge bonds with the CAA so that if they go out of business, the CAA can give refunds to people who can't travel and arrange for people abroad to finish their holidays and fly home.

Bichard Inquiry - This was the independent inquiry arising from the Soham murders, chaired by Sir Michael Bichard. Its Terms of Reference were: "Urgently to enquire into child protection procedures in Humberside Police and Cambridgeshire Constabulary in the light of the recent trial and conviction of Ian Huntley for the murder of Jessica Chapman and Holly Wells. In particular to assess the effectiveness of the relevant intelligence-based record keeping, the vetting practices in those forces since 1995 and information sharing with other agencies, and to report to the Home Secretary on matters of local and national relevance and make recommendations as appropriate." Further information available at: <u>http://www.bichardinguiry.org.uk/</u>

Bristol Inquiry - The Bristol Inquiry, chaired by Professor Ian Kennedy, was set up in 1998 to investigate paediatric cardiac services at the Bristol Royal Infirmary. The Terms of Reference were: "To inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues; to make findings as to the adequacy of the services provided; to establish what action was taken both within and outside the hospital to deal with concerns raised about the surgery and to identify any failure to take appropriate action promptly; to reach conclusions from these events and to make recommendations which could help to secure high quality care across the NHS." Further information available at: http://www.bristol-inquiry.org.uk/

BRTF - The Better Regulation Task Force is an independent body that advises Government on action to ensure that regulation and its enforcement accord with the five Principles of Good Regulation. Further information available at: <u>http://www.brtf.gov.uk</u>

BRC - The Better Regulation Commission, announced in the 2005 budget, will succeed the Better Regulation Task Force (BRTF) in January 2006. The BRC will be an independent advisory body sponsored by the Cabinet Office. As well as monitoring delivery of the reform process, including vetting departmental plans for regulatory burden reduction, the BRC will take on the work of the BRTF.

CHRE - Council for Health Care Regulatory Excellence. CHRE was established in April 2003, by the National Health Service Reform and Health Care Professions Act 2002. CHRE oversees the statutory professional self-regulatory bodies, identifying and disseminating good practice, facilitating closer working between the regulatory bodies and challenging unduly lenient

fitness to practise decisions. Further information available at: <u>www.chre.org.uk</u>

CORGI Registration - CORGI is the National Watchdog for gas safety in the UK. CORGI work is prescribed by the Health and Safety Executive (HSE). As well as operating the register of competent gas installers, CORGI investigates gas safety related complaints from the public and provides members of the public with details of local registered installers

CRB - Criminal Records Bureau. The purpose of the CRB is to help all types of organisations in England and Wales make more informed recruitment decisions. The CRB achieves its purpose by providing a service called Disclosure. This is a carefully regulated one-stop shop service that enables organisations to gain access to important criminal and other information for recruitment and licensing purposes. The CRB helps organisations to perform better by screening out candidates who may be unsuitable for certain kinds of work. In doing this it particularly helps to provide protection for children and other vulnerable members of society. Further information available at: http://www.crb.gov.uk

FSA - The Financial Services Authority (FSA) is an independent non-Governmental body, given statutory powers by the Financial Services and Markets Act 2000. Further information available at: <u>http://www.fsa.gov.uk</u>

Hampton Review of regulatory inspection and enforcement - In the 2004 Budget, the Chancellor asked Phillip Hampton to lead a review into regulatory inspection and enforcement with a view to reducing the administrative cost of regulation to the minimum consistent with maintaining the UK's excellent regulatory outcomes. This resulted in an interim report, *Reducing administrative burdens: effective inspection and enforcement*, which outlines the issues relevant to the administrative cost of regulation, and suggests possible solutions. The final report of the Hampton Review on regulatory inspections and enforcement was published on March 16 2005. Whilst more concerned with business regulation, the Review has interesting lessons for the regulation of health care. Further information available at: <u>http://www.hmtreasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cf</u> <u>m</u>

HPC - The Health Professions Council. The Health Professions Council regulates thirteen professions; arts practitioners, biomedical scientists, chiropodists and podiatrists, clinical scientists, dieticians, occupational practitioners, operating department practitioners, orthoptists, paramedics, physiotherapists, prosthetists and orthotists, radiographers and speech and language practitioners. The protected titles for these professions came into force on July 8th 2005. Further information available at: <u>http://www.hpc-uk.org</u>

GCC - General Chiropractic Council. Further information available at: <u>http://www.gcc-uk.org/page.cfm</u>

GOsC - General Osteopathic Council. Further information available at: <u>http://www.osteopathy.org.uk/</u>

OFCOM - OFCOM is the independent regulator and competition authority for the UK communications industries, with responsibilities across television, radio, telecommunications and wireless communications services. Further information available at: <u>http://www.ofcom.org.uk/</u>

OFWAT – OFWAT is the economic regulator for the water and sewerage industry in England and Wales. Further information available at: http://www.ofwat.gov.uk/aptrix/ofwat/publish.nsf/Content/navigation-homepage(ofwat)

Shipman Inquiry – chaired by Dame Janet Smith, this was the Independent Inquiry into the issues arising from the case of Dr Harold Shipman. Its terms of reference, laid down by Parliament, were:

- a. After receiving the existing evidence and hearing such further evidence as necessary, to consider the extent of Harold Shipman's unlawful activities.
- b. To enquire into the actions of the statutory bodies, authorities, other organisations and responsible individuals concerned in the procedures and investigations which followed the deaths of those of Harold Shipman's patients who died in unlawful or suspicious circumstances.
- c. By reference to the case of Harold Shipman to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision and the use of controlled drugs; and
- d. Following those enquiries, to recommend what steps, if any, should be taken to protect patients in future, and to report its findings to the Secretary of State for the Home Department and to the Secretary of State for Health.

Dame Janet's Fifth Report "*Safeguarding Patients: Lessons from the Past - Proposals for the Future*" (Cm 6394) includes recommendations about the reform of health care regulation, and in particular, reform of the General Medical Council. The full reports of the Shipman Inquiry are available at: <u>http://www.the-shipman-inquiry.org.uk/</u>

- **SSR** statutory self-regulation
- **VSR** voluntary self-regulation

REFERENCES

- 1. HM Treasury. (March 2005). *Reducing Administrative Burdens: effective inspection and enforcement* (The Hampton Review). Available at: <u>http://www.hm-treasury.gov.uk/media/A63/EF/bud05hamptonv1.pdf</u>
- 2. Section 29 National Health Service Reform and Health Care Professions Act 2002
- 3. Section 27 National Health Service Reform and Health Care Professions Act 2002
- 4. Section 26 National Health Service Reform and Health Care Professions Act 2002
- 5. Section 60 Health Act 1999
- 6. The Health Professions Order 2001
- 7. The Nursing and Midwifery Order 2001
- 8. Allsop, J. et al (2004). Regulation of the Health Professions. A Scoping Exercise Carried out on behalf of the Council for the Regulation of Health Care Professions (now CHRE) (2005). Available via www.chre.org.uk
- 9. *The Statutory Regulation of the Acupuncture Profession*. (2003). Published by POWFIH on behalf of the Acupuncture Regulatory Working Group.
- 10. *Recommendations on the Regulation of Herbal Practitioners in the UK* (2003). Published by POWFIH on behalf of the Herbal Medicine Regulatory Working Group.
- 11. Department of Health. (2004). *The Statutory Regulation of Herbal Medicine and Acupuncture – Proposals for Statutory Regulation*. The Stationery Office. <u>www.dh.gov.uk/Consultations/ClosedConsultations/fs/en</u>
- 12. Department of Health (2005). CMO Review of Medical Revalidation: A call for ideas.

http://www.dh.gov.uk/AboutUs/MinistersAndDepartmentLeaders/Chief MedicalOfficer/Features/FeaturesArticle/fs/en?CONTENT_ID=4105279 &chk=UMDpss

13. Department of Health (2005). *Review of non-medical professional regulation: A call for ideas.* More commonly being referred to as 'the Foster Review'. See Annex 2

- 14. For further information on the Foundation's regulation programme, see: <u>http://www.fihealth.org.uk/fs_what_we_do.html</u>
- 15. Stone, J and Matthews, J. (1996). *Complementary Medicine and the Law*. Oxford University Press.
- 16. Stone, J. 2005. 'Regulation of CAM practitioners: reflecting on the last ten years.' *Complementary Therapies in Clinical Practice*. Elsevier.
- 17. House of Lords' Select Committee on Science and Technology. (2000). Complementary and Alternative Medicine. HL Paper 123. The Stationery Office. <u>http://www.parliament.the-stationery-</u> <u>office.co.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm</u>
- 18. Ibid at para 5.53 <u>http://www.parliament.the-stationery-</u> <u>office.co.uk/pa/Id199900/Idselect/Idsctech/123/12309.htm</u>
- Department of Health (2001). Government Response to the House of Lords Select Committee on Science and Technology's Report on Complementary and Alternative Medicine. CM 5124. The Stationery Office. <u>http://www.archive.official-</u> documents.co.uk/document/cm51/5124/5124.htm
- 20. Reconfiguring the Department of Health's arm's length bodies

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/Publication sPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CO NTENT_ID=4086081&chk=y4UIfP

- 21. The Shipman Inquiry. Fifth Report. Safeguarding Patients: Lessons from the Patient Proposals for the Future. Cm 6394 http://www.the-shipman-inquiry.org.uk/reports.asp
- 22. Better Regulation Task Force. (1999). Self-Regulation: Interim Report. Cabinet Office. See too, the principles articulated in National Consumer Council. (1999). Self-regulation of Professionals in Health Care: Consumer Issues. NCC.
- 23. Department of Health. (2001). *Modernising Regulation in the Health Professions.* London. Department of Health.
- 24. Department of Health. Enhancing Public Protection: Proposals for the Statutory Regulation of Health care Support Staff in England and Wales. <u>http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsul</u> <u>tationsArticle/fs/en?CONTENT_ID=4085171&chk=yQsIAc</u>

- 25. Merrison Report. (1975). Report of the Committee of Inquiry into the Regulation of the Medical Profession. HMSO. For further discussion on the regulation of professionals, see Price. D. 'Legal Aspects of the Regulation of the Health Professions'. In Allsop, J and Saks, M. (2002). Regulating the Health Professions. Sage.
- 26. Department of Health. (2005). *Making safeguarding everybody's business: A post Bichard vetting scheme.*

http://www.dh.gov.uk/Consultations/ClosedConsu

27. For a full discussion of international comparators, see the O' Sullivan report:

http://www.dohc.ie/publications/regulation of practitioners of comple mentary and alternative medicine.html

- 28. For discussion of therapeutic relationships, see: Stone, J and Katz, J. 'The Therapeutic Relationship and Complementary and Alternative Medicine', (Chapter 8) and Lee-Treweek, G and Stone, J. 'Critical Issues in the Therapeutic Relationship' (Chapter 9). In Heller, T., Lee-Treweek, G., Katz, J., Stone, J. and Spurr, S. (eds). (2005) *Perspectives on Complementary and Alternative Medicine*. Open University Press and Routledge.
- 29. For discussion of the tensions involved in what counts as an acceptable evidence base in complementary health care, see Stone, J. (2002). *An Ethical Framework for Complementary and Alternative Therapists.* Routledge. Chapter 8.

ANNEX 1

CMO CALL FOR IDEAS

I. Should doctors' performance be assessed in addition to, or as part of, the annual NHS appraisal? What purpose should appraisal of clinical practitioners have: should it be primarily for governance, with a mainly summative structure and handling, or should it be – as at present – primarily for developmental purposes, with a mainly formative structure and handling? Can it do both at the same time? How might small practices and departments be supported in this area? What form should assessment take?

II. What practical measures would assist with establishing that a doctor continues to be able to provide competent and safe services? Should 360° reporting be introduced by the NHS as part of appraisal? Should there be a confidential reporting system? Should doctors record their experience, learning or educational events in a log-book? Who should be involved in the assessment process?

III. How can patients and the public contribute to the maintenance of standards and competence? Should their views about their medical treatment be sought routinely? Or on a sample basis?

IV. How should lessons learnt from patient complaints be fed into the appraisal system? How can staff be encouraged to identify and report poor performance or unacceptable conduct?

V. What should be the core purpose(s) of revalidation? Are the GMC correct when they say that the purposes are to contribute to raising standards by requiring doctors to demonstrate that they have reflected on their practice; and to protect patients by securing confirmation that doctors are up to date and fit to practise, by providing a backstop where local systems do not exist, or exist but are inadequate; and through robust quality assurance mechanisms?

VI. In the light of this, what should the broad structure of revalidation be? Should it be a screening ('assessment level 1') process aimed at identifying practitioners at risk of having a fitness to practise problem; aimed at actually identifying dysfunctional practitioners (case finding, or 'assessment level 2'); or, as the legislation currently provides, aimed at evaluating fitness to practise (diagnostic or 'assessment level 3')?

VII. What attributes (knowledge and skills), behaviours and attitudes should doctors have to demonstrate to maintain their registration? Are there any other relevant attributes which should be assessed?

VIII. How should the required standards be set? Should there be objective criteria? How should these be identified and measured?

IX. Should there be a core evidence set for revalidation? How should it be defined?

X. How should 'failure to revalidate' be handled, in the light of topics I and II above? How can we avoid 'double jeopardy', with repeated assessments?

XI. When a doctor's fitness to practise has been called into question what arrangements should there be to protect the public? How should the GMC monitor the compliance of conditions it has imposed on a doctor? Are there any extra safeguards for a doctor being retrained above those required for a doctor in training?

XII. What arrangements are needed for doctors whose fitness to practise fails to meet the necessary standard? Is retraining a realistic option for all doctors? Who should pay for this? What arrangements should be for doctors to move to other duties and to provide exit strategies?

XIII. What else is needed to provide patients and the public with the assurance they need to maintain confidence in the competence and safety of medical practice?

XIV. How should information on practitioners' fitness to practise be held and made available, including information from appraisal, revalidation and fitness to practise (including local disciplinary procedures)? Should this be a single national database or a collation of local NHS and other databases (e.g. the GMC register)?

XV. Should the GMC continue to be a complaints-handling body which receives complaints directly from any source, or should it be a body to which complaints are normally only referred by health care organisations and other public bodies where they have passed a threshold indicating that the doctor may be unfit to practise?

XVI. Will the complaints portal recommended by Dame Janet, together with appropriate public information about the differing aims of complaints procedures and fitness to practise procedures, resolve current public uncertainty about how and where to make a complaint; or is better role-definition for the various organisations involved, expressed where necessary in legislation, essential? training.

XVII. What should the regulation of the medical profession look like?

XVIII. What should be the role and structure of the General Medical Council in the future? What should the primary purpose of the council, currently composed of 35 members, be: governance and policy development, i.e. more like a publicly accountable board, or delivery, i.e. directly involved in exercising the GMC's powers and functions? In either of these settings, what should its size be and how should members be appointed? If its function is governance and policy development, who should carry out the work of the council on delivery? If its function is delivery, how should these powers be delivered? In fitness to practise, the following key components are currently delivered by the GMC: setting standards of conduct, policy and procedural

rules, investigation of complaints, case presentation, adjudication. How should these elements be organised in the future?

XIX. Do we have the right balance between regulation and freedom to practise (including innovation)?

XX. What alternative models are there in other fields of endeavour in the UK or elsewhere? How could these be adapted for the medical profession in the UK?

XXI. Should the regulation system be made more accountable and intelligible to the public? What should be the relationship between the GMC and Council for Health care Regulatory Excellence (CHRE)? How should the effectiveness of that relationship be evaluated? Should the GMC be made directly accountable to Parliament, as Dame Janet has recommended?

ANNEX 2

REVIEW OF NON-MEDICAL PROFESSIONAL REGULATION: CALL FOR IDEAS (' THE FOSTER REVIEW')

The Secretary of State has asked me to consider and provide advice about the regulation of the non-medical health care workforce. The specific terms of reference for my review are attached. I have established an Advisory Group to help me with this task. Details of its membership are annexed.

This "*Call for Ideas*" is to seek views on the issues that my review will cover, to help inform me and the Advisory Group in considering options for change.

The "*Call for Ideas*" in particular seeks views on the six key themes I have identified as central to my review:

- 1. What measures are needed to demonstrate practitioners' initial and continuing fitness to practice?
- 2. What changes are needed to the process of carrying out fitness to practise investigations in order to maximise public safety, the quality of health care, fairness to registrants and satisfaction of complainants?
- 3. How can we best ensure that support workers provide safe and reliable services to patients? Should they be subject to a formal and fully developed system of regulation?
- 4. How should new and extended professional roles be regulated?
- 5. How does regulation fit into its wider context? How does it relate to the new workforce systems (Agenda for Change, the Skills Escalator, etc) and to the wider network of strategic health care priorities and modernised systems, including the extension of IT?
- 6. What changes are needed in the structure, functions and number of health care regulators?

I would welcome ideas by e-mail or by letter on the key themes identified above or on other issues relevant to my review, by 29 July.

Please email submissions to hrdlistening@dh.gsi.gov.uk

Or write to

Andrew Foster Director of Workforce Department of Health Richmond House 79 Whitehall London SW1A 2NS

ANNEX 3

FEATURES OF EFFECTIVE VOLUNTARY SELF-REGULATORY BODY

Features of an Effective Voluntary Self-Regulatory Body
An effective voluntary self-regulating professional body:
 maintains a register of individual members or member organisations sets educational standards and runs an accreditation system for training establishments maintains professional competence among its members with an adequate programme of Continuing Professional Development; provides codes of conduct, ethics and practice has in place a complaints mechanism for members of the public has in place a disciplinary procedure that is accessible to the public requires members to have adequate professional indemnity insurance has the capacity to represent the whole profession
 includes external representation on executive councils to represent patients or clients and the wider public interest

Source: Budd, S. & Mills, S. (2000). *Regulatory Prospects for Complementary and Alternative Medicine: Information Pack*. University of Exeter (2000), on behalf of the Department of Health.

Reprinted from the House of Lords Select Committee Report at para 5.15

http://www.parliament.the-stationeryoffice.co.uk/pa/ld199900/ldselect/ldsctech/123/12308.htm