



# Professionally-led regulation in healthcare – just a cosy club?

Edited by Jessica Asato

The regulation of healthcare professionals is once more in the spotlight with the fifth report of the Shipman Inquiry. The healthcare regulatory environment has been in a process of reform since the Bristol Inquiry, in particular a new overarching body, the Council for Healthcare Regulatory Excellence, has been set up to scrutinise decisions by regulators and share best practice. A number of regulators have also increased their lay membership and initiated continuing professional development processes. But at time when the regulatory bodies for healthcare professions have come back under scrutiny, has the sector reformed enough to generate confidence, and is there a need to look more closely at the model of professionally-led regulation in healthcare as a whole?

The collection includes a foreword written by Rt Hon. John Hutton, Minister of State for Health; and essays by Sir Graeme Catto, General Medical Council; Lord Hunt of Kings Heath, National Patient Safety Agency; Janet Paraskeva, The Law Society; Simon Williams, The Patients Association; Frances Blunden, Consumers' Association; and Charles Miller, SMF Business Forum Regulatory Best Practice Group.

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EDITED BY JESSICA ASATO

THE SOCIAL MARKET FOUNDATION

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SOCIAL MARKET FOUNDATION

November 2004

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## FOREWORD

RT HON. JOHN HUTTON MP, MINISTER OF STATE FOR HEALTH

I am pleased to introduce this collection of essays on an important subject. Since 1997 the Government has stressed the importance of independent regulation for healthcare professionals. It is essential to our programme of clinical governance, which sets out to improve the quality of clinical service throughout the National Health Service. As we said in *Reconfiguring the Department of Health's Arm's Length Bodies* (July 2004), about the regulation of services:

"Patients need to be able to rely on the quality and consistency of the services they receive. This is not something that can be managed from Whitehall. Services should be delivered locally within national standards. Regulators have a key role to play in making sure that local services really do meet those standards so that patients and users can rely on them."

This principle of independent regulation applies as much to the statutory regulators of the professions, such as the GMC, as it does to arm's length government bodies like the Healthcare Commission. Independence gives a regulator the freedom to focus purely on protecting the public, and can give the public more confidence that it is doing so.

I also believe that ownership of standards by the profession, about which Sir Graeme Catto writes convincingly in this collection, is important. Failing to engage the profession in the development and maintenance of standards would undermine the effectiveness of regulation, which is far more likely to secure high quality practice if it is built on the force of individual conscience.

However, as Professor Catto says, regulators must avoid giving the impression of being cosy clubs for the benefit of their professions. Professional regulation must serve the wider public interest. In Government we see our task as supporting reforms which will fully advance this overriding public interest. As we said in *The NHS Plan* in 2000, regulatory bodies had to change, so that they:

- are smaller, with much greater patient and public representation on their governing bodies,
- have faster, more transparent procedures, and
- develop meaningful accountability to the public and the health service.

Since then we have worked energetically with the GMC and other regulators of health professions to modernise the legal frameworks, such as the Medical Act, within which they operate, in order to secure these goals. Progress has been good but there is still further to go.

In order to support the reform programme without infringing the independence of the statutory regulators, we decided to establish a body with an independently appointed lay majority, now called the Council for Healthcare Regulatory Excellence (CHRE), to oversee their work. CHRE was set up by Act of Parliament in 2003 and its own independence from Government is guaranteed by law. Its mission is to protect the public interest, promote best practice and progress regulatory excellence. It has made a promising start, described in its first annual report which was laid before Parliament and published on CHRE's website<sup>1</sup> on 8 September 2004.

We expect that CHRE's work will strengthen professionally-led regulation and help rebuild public confidence, for example by promoting more consistent practice between regulators. It may need to develop its role over time, as part of the reform programme we recently described in *The NHS Improvement Plan* (June 2004). While the Government does not at present plan to extend CHRE's functions, we will keep this under review in the light of regulatory developments.

Independent regulation of the healthcare professions must always be seen as a means to secure high standards of healthcare and public confidence. Over the last seven years the Government has acted decisively to secure the high quality regulation which patients and public have a right to expect. We will continue to do so.

<sup>1</sup> [www.chre.org.uk](http://www.chre.org.uk)



## INTRODUCTION

JESSICA ASATO, SOCIAL MARKET FOUNDATION

With the fifth report of Dame Janet Smith's inquiry into the Shipman murders being published in the near future, there is no more topical time to be considering the issue of the regulation of healthcare professionals. While public trust in doctors remains high, in fact at its highest level for 20 years,<sup>2</sup> the traditional image of the selfless, hard-working, life-giving medical professional has certainly been shaken by successive revelations of doctors abusing their position of trust. The Bristol Inquiry, Harold Shipman, Clifford Ayling, and many other high profile examples of doctors acting in a criminal or negligent way, have undermined confidence in the ability of our healthcare staff.

But the worry is that in trying to be seen to react to the horrors of a few infamous cases, politicians will seek to smother healthcare professions with external regulation and in concentrating so much on the high profile cases they will ignore the more common cases of general poor performance by health professionals. Of course the public interest must be paramount in any decision taken about the regulation of health professionals, but today's picture is very different from that presented in the popular TV series in the '60s, *Dr Finlay's Casebook*. In 1960 there were just 17,080 doctors on the General Medical Council's register, in June this year there were 214,013. In 2002 GPs undertook 291 million consultations<sup>3</sup> compared to 196 million in 1975.<sup>4</sup> Patients nowadays are more inquisitorial, less deferential, and have more access to information about treatments and the standards expected from health professionals than ever before. Any attempt to regulate, therefore, must take into account the reality of the environment in which health professionals operate today.

Recent changes in the regulation of health professionals have sought to reflect this new environment. The Council for Healthcare Regulatory Excellence (CHRE)<sup>5</sup> was set up in 2003 following a recommendation from the Bristol Inquiry. Its remit was to protect the public interest, and promote best practice and consistency in nine regulatory bodies which oversee healthcare professionals. So far it has carried out an audit of the regulatory bodies which

highlighted areas where best practice could be shared, increased communication between the regulators, and considered 213 disciplinary decisions by the regulators. It is of course early days, but one of the challenges for the CHRE will be to cope with some of the possible professions who may wish to be self-regulated in the future.

Regulatory bodies themselves have also reacted to recent developments. The General Medical Council (GMC), for example has introduced a new licence to practice which will start in 2005. After being registered, the licence to practice must be supported by revalidation every five years to ensure that doctors are practising medicine according to GMC guidelines. This will help to ensure that doctors' skills are kept up to date and any serious problems can be identified earlier. Other regulators are developing continuing professional development (CPD) processes. Many regulators have increased their lay membership. The GMC slimmed down its council and increased its lay membership to 40% in 2003 and the RPSGB<sup>6</sup> will soon increase its proportion of lay members to 35%. The regulators are also making an effort to reach out more widely to the public. The NMC (Nursing and Midwifery Council) for example, has developed a public involvement strategy, which includes involving representatives of consumers' and patients' organisations in committees, creating a panel of consumers, improving access to information, and strengthening links with relevant organisations. The GMC has also created a patient and public reference group.

This collection of essays looks at the challenges which still face the regulation of healthcare professionals, and in particular assesses whether the model of professionally-led regulation can continue to work in the public and patient interest. The main argument against giving professionals the lead over their own regulation is that they cannot be seen to be acting in anyone's interest except for their own. Human nature, so the argument goes, prevents them from putting patients' interests before that of the profession. Frances Blunden from the Consumers' Association argues in her essay, that the fact that the GMC is funded by the profession gives the impression that it is in 'the pay' of doctors and will therefore make decisions on that basis. Similarly, because members of the profession are elected to the Council, it could be inferred that they are there to represent the interests of their electorate, not the public as a whole. The only way to make the GMC truly transparent, Blunden argues, is to make the body independently funded, and dominate it by lay members, so that the model is not professionally-led regulation, but 'co-regulation'.

Sir Graeme Catto puts forward a defence of professionally-led regulation arguing that doctors need to have ownership of their regulator, and that force of conscience and self-policing would be driven out by externally-led regulation. Janet Paraskeva agrees with this perspective from her role as President of The Law Society, another professionally-led body which is also in the process of reform. She writes that belonging to a professional body means “subscribing to an ideal, not just obeying rules imposed from without,” which imposes a higher ethical standard on practitioners than mere rules ever could. The alternative to professionally-led regulation, it is argued, would lead professionals to become defensive in their jobs rather than to act in the best interests of their clients. Both Graeme Catto and Janet Paraskeva admit, however, that public involvement is crucial in a regulatory system, to help maintain the regulator’s independence and to inform its work from a consumers’ perspective. In particular it is acknowledged that if professionally-led regulation is to work not just in practice, but seen to work from the public’s perspective, regulators must do their best to get away from the notion of a ‘cosy club’ and continue to make the profession more transparent and accountable.

It is important as well that at a time when the thrust of regulation is to make it less complex and to carry out regulatory impact assessments, as detailed by Charles Miller in his essay, the professionally-led regulators are treated in the same way. Knee-jerk reactions based on poor evidence do not inspire confidence in regulators, and any change in professionally-led regulation must be in the interests of the public rather than for reasons of political expediency.

The process of healthcare regulation could also be made substantially simpler if the complaints system itself was less complex, as is argued by Simon Williams from the Patients Association. At the moment there are a myriad of different organisations who deal with healthcare complaints: the Patient Advisory Liaison Service, the Independent Complaints and Advisory Service, the Healthcare Commission, the Council for Healthcare Regulatory Excellence, and that’s excluding the regulatory bodies themselves. It has long been argued that there should be a single complaints gateway so that patients avoid being pushed from pillar to post and have their complaint addressed straight away. Such a gateway could provide the public with information about which is the most appropriate organisation to complain to, and also provide independent expert advice for the complainant. It would also make it easier for the

complaints bodies themselves, who have to deal with patients who have chosen the wrong organisation to complain to.

If a real difference is to be made to regulation of healthcare professionals in the long-run, however, more emphasis needs to be placed on ensuring that mistakes and errors of judgement are not allowed to happen in the first place. As Lord Hunt, Chairman of the National Patient Safety Agency argues in his essay, the NHS needs to develop a culture where professionals can admit mistakes so that lessons can be learnt. There also needs to be a cultural change to allow patients to feel entitled to challenge health professionals about their treatment, or to make a complaint if they feel badly treated. The ‘Clean Your Hands’ campaign, for example, which encouraged patients to ask staff whether they had washed their hands, resulted in a much greater level of cleanliness amongst staff, and made patients feel more responsible for their own healthcare.

In conclusion, it becomes apparent that there is no easy substitute for having trust in the ability of healthcare professionals. There are ways of making regulatory bodies more transparent and of reforming complaints procedures to make it easier for patients to find redress when mistakes have been made. But a profession which is motivated by an “inherent ethical commitment” as Janet Paraskeva writes, is far preferable to a profession which is motivated by simple compliance with minimum standards. Professionally-led regulation may not be perfect, but it is the best way to allow professionals to work safely and in the interests of the public.

<sup>2</sup> MORI Social Research Institute 23rd March 2004. MORI found more than nine in 10 members of the public (92%) trust doctors to tell the truth. This is higher than the rating for any other professional group included in the survey, and the highest since it began in 1983.

<sup>3</sup> Office of Health Economics. Compendium of Health Statistics, 15th Edition 2003/04. London: OHE, 2004

<sup>4</sup> Living In Britain, Results from the General Household Survey ONS

<sup>5</sup> Formerly the Council for the Regulation of Healthcare Professionals established by the NHS Reform and Health Care Professions Act 2002

<sup>6</sup> Royal Pharmaceutical Society of Great Britain



## CALLING TIME ON THE COSY CLUB

SIR GRAEME CATTO, PRESIDENT, GENERAL MEDICAL COUNCIL

I believe that medicine is far too important a subject simply to be left to doctors. Self-regulation, without public involvement, has been shown in the past to be a flawed model, which can lead to professions becoming increasingly isolated and losing touch with society. I know that self-regulation contributes to a loss of the public's trust in professions. A cosy club, I think, is the least of its shortcomings.

I have to say that from General Medical Council's perspective it has not been terribly cosy over the last couple of years and it is probably not going to get any cosier in the immediate future. I do not believe at all in self-regulating professions but I do believe very strongly in professionally-led regulation. Regulation that protects patients by fostering professionalism in doctors and other healthcare professions, and by involving patients and the public. In countries that do not follow this model, the professions by and large survive unscathed, but the interests of patients are not well served and standards for patients by and large decrease. We can think of quite a number of different countries' where that pattern has evolved over time.

If you look at the GMC's guidance on standards and ethics, '*Good Medical Practice*', which is the core guidance for doctors, and really is the foundation of all the recommendations that come from us, the very first statement is that as a doctor, you must make the care of your patient your first concern. I believe that really sums up all the important parts of this debate. The GMC has taken a battering in recent years and I suspect with the inquiries this summer, and the Shipman Inquiry which will be reporting shortly, it is not out of the woods yet. However, there is no doubt that we are implementing a substantial programme of reforms. The pieces are now in place, I believe, to make medical regulation in the United Kingdom a beacon for regulation in other countries in the world. We are well placed, I think, to protect patients in the best possible way.

### Clear standards

Of course our vision for regulation is based on quite a number of important

concepts. First of all, as I have indicated already, we need clear standards of professional practice, which are determined quite independently of government, the NHS or any of the other healthcare providers and employers. We in this country – and we in the medical profession and patients generally – take that independence for granted, or at least we do for the moment. But I think we need to take care in the months and years ahead. The last thing we should be at the moment is complacent. We need, of course, to have substantial public involvement in the development of those standards to ensure that they are completely in line with the views of the non-doctors in society.

Nevertheless, ownership of the standards by doctors – and we expect them to adhere by these standards – is absolutely essential. No mechanism of external review could possibly take account of the myriad of consultations between doctors and patients that take place in the course of a year, and that is true for the other healthcare professions as well. Doctors are no different in that regard from many others. We need, of course, to have systems to ensure that there is compliance with those standards throughout a doctor's career, not just at the undergraduate and the training periods, but also for doctors in long-term clinical practice. We need to have mechanisms that allow us to take corrective action before things go seriously wrong. Educational programmes are important to inculcate those standards and they are important throughout a doctor's career, from the first year in medical school right through to retirement from medical practice. Education is not just for undergraduates and for doctors in training, it is for all doctors.

We need arrangements, of course, to ensure that doctors and employers work closely together, and in particular that they share appropriate information at the right times. The responsibilities of the regulator, the General Medical Council in this case, and the employer are different, but it is absolutely essential that they are complementary. We need to have transparency of process, criteria and decisions so that everyone can understand, doctors included, just what is being done and why. We need plans here in terms of policy, and in the outcome of individual cases that go through fitness to practice procedures. Clear accountability is part of that process. We report what we do and we plan openly in public session. We report to Parliament fully and honestly and the public are well capable of deciding and judging whether we are performing a reasonable job or not. It is not enough merely to indicate that we are discharging our functions. We need to have involvement of the public and we need to be aware that they can influence what we are doing.

### Public partnership

The model that can best achieve all of these aims is, I believe, professionally-led regulation in partnership with the public. It sounds a bit of a mouthful but it is precisely what the General Medical Council is now doing and has been doing for the last few years. We have a unique role. When inquiry chairman Professor Ian Kennedy reported on the problems at the Bristol Royal Infirmary, he defined regulation as ‘encapsulating all of the systems which combine to assure the competence of healthcare professionals: education, registration, training, continuing professional development and revalidation, as well as disciplinary matters.’<sup>8</sup> The GMC covers all the links in that particular chain and must, I think, continue to do so. We do accept, and it is perfectly clear, that we are not the only organisation that does this and does so in the interests of the public and patients. Other organisations – the NHS itself, the BMA, the Department of Health and a variety of patient and consumer groups represent important bodies. But only within the GMC are all these concepts, all these threads, brought together and a proper balance struck, independent of any sectional interest and in the public interest.

So in order for the GMC to be able to work effectively, we have become a completely different organisation – a smaller council with a substantially increased lay input. We have launched a series of world leading initiatives such as revalidation. Although I realise that as a concept revalidation is occurring elsewhere in the world, there is no other country that is linking the concept of doctors having a licence demonstrating that they are up-to-date and fit to practice on a regular basis with their ability to work as a doctor. Revalidation is being led by the United Kingdom, by the General Medical Council, and it is being watched with fairly great interest – not just within this country, but worldwide.

The Council is becoming much more strategic, trying to anticipate events and developing policies rather than simply reacting to what has happened in the past. Lord Andrew Phillips recently wrote movingly about professionalism. He said that the essence of professionalism is being able to call upon the honour, the probity and the principled judgement of the practitioner, and that any fully respecting profession would profess just that, and take steps to deal with inevitable failures. The alternative, he put it, is external regulation, and for at least the last quarter of a century it has been clear that that gives rise, as social economist Fred Hirsch said, to a ‘rising mass of codified petty regulation, swollen by the need for rules to enforce rules and to counter their avoidance.’<sup>9</sup>

It is not a bad phrase and it is not a bad concept when you look at what is happening to medical regulation in other countries and potentially in this country. Then, it goes on to say, of course the very complexity of an externally-led regulatory process is inherently self-defeating. It becomes far too complicated ever to deal with the myriad of consultations between a healthcare professional and a patient. Worse than that, it tends to drive out self-policing and the force of individual conscience.

### Collective conscience

Of course organisations like the General Medical Council and other regulators are actually the collective conscience of the profession and work in that way. I know that when we look at newspapers or television we are much more concerned with doctors who are performing badly rather than doctors who are performing well under difficult circumstances. Though they represent a small proportion, we do have to grasp the nettle of the dodgy doc, and we need to spot them as early as we possibly can and certainly before they damage patients. So we are working very much more closely than ever before with the NHS and with other providers of healthcare, so that if a complaint comes our way we ensure that the employer knows about it and we have a dialogue about who is best placed to deal with the matter. When it falls to us, and many of these cases do fall to us, we have streamlined our disciplinary process and in the meantime we have completely eradicated the backlog and delays which used to be a feature of any conversation about the GMC.

So I believe that this form of regulation, this professionally-led regulation in partnership with the public, which Parliament endorsed as recently as 2002, is the right way forward. It is fostering, I think, a new model of professionalism in medicine based on clear standards and values, on respect of the patient and lifelong learning. Of course you could have a lay body that had professional advice and ask it to regulate the profession, but it is likely to alienate those you most wish to regulate. Medicine cannot really be effectively regulated without the full commitment of doctors to the values underpinning their work, and those values must be embraced, not just bolted on as an afterthought in a climate of suspicion and alienation.

Professions and professionals go together by definition because of their particular skills and expertise, but there is no room any more for paternalism and remoteness, which were, I think, a characteristic of medicine until comparatively recently. We do not want doctors to think that they are God –

they certainly are not – nor to have an inflated view of their standing, and so we should not encourage those who want to cling to an outmoded paradigm of the all-knowing, benevolent, wise doctor and grateful, subservient patient. 'Dr Finlay's Casebook' was a good television programme, but Dr Cameron was a particularly poor role model. So to conclude, we should not let worldly wisdom grow into cynicism. Society needs committed, caring, competent doctors. I believe strongly that the General Medical Council will make professionally-led regulation in partnership with the public meet the needs of modern society.

*Sir Graeme Catto's speech was given to the SMF/GMC Seminar 'Professionally-led regulation in healthcare – just a cosy club?' on 27th May 2004.*

<sup>7</sup> Examples can be found in Eastern Europe and the Middle East

<sup>8</sup> *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 – 1995* Command Paper: CM 5207

<sup>9</sup> Hirsch F. *Social limits to growth*. Cambridge, Mass: Harvard University Press, 1976

## CO-REGULATION, TRANSPARENCY AND ENGAGEMENT IN HEALTHCARE

FRANCES BLUNDEN, CONSUMERS' ASSOCIATION

Consumers' Association has a long-standing interest in the regulation of both markets and professions across a wide range of services. We have also undertaken significant work on the regulation of healthcare services and professionals. Indeed, our study of the General Medical Council and its complaints processes was cited by the GMC's past president, Sir Donald Irvine, as a key motivator of recent reforms in this area.

Our approach to regulation is underpinned by a belief that the only possible rationale for any form of statutory regulation is the promotion and protection of the public interest. That has to be the starting point – whether it is regulation of markets to make them work more effectively or to promote competition, to temper the power of one group in society, or to protect the public from unscrupulous or potentially dangerous practices.

A number of factors are key to enabling regulators to deliver effective regulation in the public interest. They must have:

- Clearly defined objectives that set out their responsibilities and duties with regard to the public interest
- A dedicated structure that is independent of the industry (or in the case of the GMC – the profession)
- Strong independent representation on the Board or Council, including representation of consumer interests
- Adequate resources to ensure its independence from sources that do not compromise its objectives
- Mechanisms for wide consultation and engagement, particularly for listening to the consumer voice

- Clear and intelligible rules that set standards and are supported by effective mechanisms for monitoring
- Appropriate redress mechanisms, with accessible and well-publicised complaints procedures
- Proper public accountability with regular reviews of their performance against agreed criteria.

Regulators must not only command confidence of the professions, they must also command public confidence that they are operating in a fair, open and transparent way. Part of that means access to information that the regulators use and base their decisions upon and that should be in the public domain. This suggests an approach to regulation that is neither professionally-led or self-regulation, but is in fact co-regulation. This depends on the involvement of all the different groups of stakeholders in the regulatory process, and operates as a more equal partnership than any existing regulatory approaches.

It would be wrong to detract from what the GMC and other health regulators have done over the last ten years to improve their processes, procedures and approach, or from the real commitment that some professionals who are associated with healthcare regulation have to putting patients first. Introducing some of the GMC reforms such as revalidation, license to practise, and reform of the Council, with much greater lay representation, have been important changes. But these changes have taken place against the backdrop of Bristol, Shipman, Ayling and Ledward and the message has been written fairly large for the professions – ‘change or be changed’. Despite these reforms there are still a number of structural issues that need to be addressed.

The first issue is whether the GMC and other healthcare regulators can really be the proper custodian of public interest while they are solely funded by the professions? It is interesting to see some of the attitudes to the reforms looking through the pages of *Pulse* or *Hospital Doctor* – here doctors are actively questioning the role and purpose of the GMC. There is an enormous sense of grievance in some quarters of the medical profession that the GMC is failing to meet their interests when they are the ones who are paying for it.

But does funding by the industry (or the profession) condition the approach of the regulator? Certainly, it often gives the appearance to the

public that it is in the pay of the industry. This is a criticism that the Consumers' Association has levelled particularly at regulators for the financial services and pharmaceuticals industries, and often appears to be the case in the healthcare field. It also undermines the potential for the regulator to be seen as truly independent and to take a robust stance on crucial issues. There is still a feeling among many of the public that the GMC is run by doctors, for doctors, and its policies and procedures are about protecting the interests of doctors, rather than those of the public.

To overcome this problem, some element of the regulation should be paid for through the public purse. Perhaps the best example of a public interest regulator is the Food Standards Agency, which is an independent government agency that is charged with protecting the health of the public and interests of consumers in relation to food. Its stated guiding principles are putting consumers first, being open and accessible, and being independent. While the FSA is not perfect, it is a useful model for other regulators, not least in its approach to openness and transparency in its operation.

The second key issue is whether the governance structures are appropriate to deliver regulation in the public interest? With several of the regulators for the health professions, the professional council members are elected by the profession. This tends to engender a feeling that they are representatives of that particular profession or constituency. Additionally, elected representatives do not have to go through the same selection process as lay members of being gauged against the public interest. But elected members of the regulatory body are not there as representatives or delegates of the profession, they are there to ensure that the public interest is promoted.

Lay members on these bodies tend to be very much the junior partners. The chair is always a professional and professionals are always in the majority, whether it is a majority of one as in the case of the Nursing and Midwifery Council (NMC) or the Health Professions Council (HPC), or whether it's 60-40 as in the case of the GMC. Moreover, on the NMC and the HPC, there is the opportunity for the professionals to have an alternate if they can't make a meeting – this doesn't exist for lay representatives so if they are unable to attend, the lay voice is further diminished.

Additionally, 'lay' in this context encompasses a wide range of interests, including other health professions and health service managers. So lay members are not just the public or patients, they represent a whole range of other interests. There is also a danger that being a lay representative can

become a bit like a job, and there are real questions about how to ensure lay members keep in touch with and are accountable to the public.

But lay representation on the Board or Council is only part of the equation. What is also needed is a range of different and creative tools to effectively engage the public in regulation and these processes.

It is not enough just to have a patient reference group that meets every two months in London. How can that be truly representative of the patient and public interests? It is often easier for regulatory bodies to approach the 'usual suspects'. A few years ago the NMC adopted a slightly more creative approach, trying to engage a wide variety of stakeholders and patient groups from different regional bases and different groups within the population. That is the sort of outreach that should be encouraged and copied.

Neither is it enough just to issue consultation documents (which seem to emanate regularly from all the regulators). These documents are often in impenetrable language, with short consultation periods. If I find it hard to engage with them on occasions, how can you expect the public to engage effectively in that process? Much more can and should be done to try to engage with the public, on their terms, rather than what makes procedural sense for the organisation or the profession. Only when regulators do this can we begin to have truly patient-centred regulation. A further problem is the difficulty the public has in accessing processes and information. For example, it is almost impossible to find out where a doctor who has been reported to the GMC is in the process, even when a public hearing has been planned.

The public also find it very difficult to understand the logic that underpins screening decisions. Using the criminal burden of proof (beyond reasonable doubt) weights the process very much towards the professional, rather than a precautionary approach of protecting the public and the public interest. The complainant has no right of appeal if they feel that what they put forward hasn't been dealt with fairly, whereas the professional does have that right.

The situation has been made worse by the Human Rights Act (HRA), which has been used by both individual and groups of professionals to argue that regulatory bodies are curbing their right to pursue their chosen profession. Because doctors often have professional indemnity insurance, they are able to use the HRA to challenge the regulatory bodies. There is a real danger that the HRA can be used to ensure that the professional interest is superior, or to override the patient interest.

Perhaps the biggest question over the effectiveness and efficacy of the current systems for regulating the health professions is whether the current processes for holding the regulators accountable in terms of their public interest role are sufficiently robust? The answer to that is probably no. Although matters have improved since the establishment of the Council for Healthcare Regulatory Excellence, there are still no effective measures for holding the individual regulators publicly accountable for their work.

The time has now passed for the old model of regulation, which is based on regulating the individual professions. We need a more accountable, comprehensive and independent regulatory system, which has an integrated approach to professions across the NHS and the private sector. It would provide a comprehensive framework that brings coherence and consistency to the regulation of professions. It should be based on the principles of co-regulation, rather than professionally-led regulation and should be under the leadership of a lay chair. The initial arguments against such an approach are that it would have to be a vast and bureaucratic body, but it could be made effective by ensuring a more localised or regional structure at the level where the professional is actually operating. This would also integrate more effectively with complaints and disciplinary processes.

There needs to be a more systematic and creative approach to achieving real public engagement, with roadshows, surveys, and active engagement of patient groups. There also needs to be a real commitment to making this work and to valuing what comes up through this process as much as what comes out of the processes used to consult the professions.

The processes and procedures of professional regulation need to be made accessible to the public so that they're less daunting and are easy to contact when needed. It is often very difficult actually to get through to any of the regulators simply to ask a question. Similarly, there is the question of what information is available to the public and how that it is disseminated. You should be able to look on the internet or in a library for information about professionals with a licence to practice, including any restrictions on the sort of practice they're allowed to undertake.

My conclusion is, yes, professionally-led regulation is no longer the cosy club that it was. But it still has some way to go and more light needs to be let into its inner recesses before healthcare regulation can be seen to be operating truly in the public interest. That is not just in the interest of the public, it is also in the interests of good professionals.

## AN EQUAL PARTNERSHIP BETWEEN PATIENTS AND PROFESSIONALS

SIMON WILLIAMS, THE PATIENTS ASSOCIATION

The GMC's slogan Protecting Patients, Guiding Doctors represents the real shift that has occurred in the regulation of doctors over the past few years. But for many patients, that shift was long overdue. For too long patients felt ignored, unrepresented, and unequal. Recently the balance has shifted more in favour of the patient, for example, through increasing lay membership of the GMC to 40%. This has been a good start in one respect; it ticks the box for public involvement, but not for *patient* involvement. We should know by now that involving patients means more than getting them to sit on a committee or a forum. Patient involvement should mean the creation of an active partnership between patients and the medical profession where they are treated on equal terms and feel that the system is working, not in the interests of the professional, but in *their* interests.

In particular we should think more about involving patients better *before* something goes wrong with their healthcare. Instead of always focusing on the aftermath, we must create a culture where patients feel comfortable asking questions and voicing concerns. It's important to emphasise that doctors can learn from their patient's experience and vice versa. There should also be clearer information about patients' rights and what they can expect from a complaints process, and a greater willingness on the professional's part to be scrutinised. Most importantly, however, is reforming the process by which patients make their concerns known when something goes wrong.

Recent figures from the National Patient Safety Agency estimate that a total of 400,000 avoidable adverse incidents take place in the UK every year, resulting in 40,000 deaths annually. Nationwide, patient safety incidents – including medication errors, treatment errors and hospital infections equate to more than 110 deaths each day. Breakdowns in patient safety are thought to be Britain's fourth biggest cause of death after cardiovascular disease, cancer and respiratory disease. Daily they account for more deaths than both road traffic accidents and

accidents in the workplace combined. The total expenditure (damages and costs) on clinical negligence in England amounts to £422.5 million and this is despite the number of clinical negligence claims received in England in 2003-2004 dropping by 20% from the previous year to a total of 6,251. Such a cost in human and financial terms must be the responsibility of us all to help address.

When patients' healthcare goes wrong there are many possible causes: errors by individual health professionals or, more likely, systems failure of some kind – for example poor staff management, inadequate handover procedures between shifts or maybe simply an unpredictable adverse drug reaction. If the complaint is about a systems failure, an administrative error or a minor question of judgement by a health professional, then the NHS complaints procedure is probably the most appropriate way of resolving the matter. The problem is that while those in the industry may know that regulatory bodies only consider investigating conduct if a doctor's fitness to practise is called into question, patients don't always know this and won't know who to complain to. Even if they do, they may not have the energy to pursue the often lengthy NHS complaints procedure to its conclusion, which can take many months or even years if the complaint goes as far as the Health Ombudsman.

Imagine a patient in a situation when something pretty serious has gone wrong with their healthcare and that their doctor has serious professional performance issues. The likelihood is that they will be a bit scared and worried about the consequences of voicing their concerns. They will hear stories that they might be being struck off by their GP if they complain. They may be reluctant to turn to somebody in authority and even if they were confident enough to challenge the system, their contact with the health services will be pretty limited. They probably would have no idea what a Patient Advisory Liaison Service (PALS) or The Independent Complaints and Advisory Service (ICAS) is. They are certainly unlikely to have heard of the General Medical Council or the Patients' Association. The jargon of local resolution, regulation, and so forth is likely to bamboozle them. In the end they won't know where to go and will simply give up.

In trying to provide patients with a number of different options we have inadvertently encouraged patients to wander in the wilderness. We have created so many pillars and posts for patients with genuine fears and concerns to bounce between. From PALS and ICAS, local resolution to regulators, the Healthcare Commission and the Council for Healthcare Regulatory Excellence (CHRE), to the myriad of other avenues that face a patient, they all add to the confusion and frustration when something goes wrong.



A key part of the reforms to the NHS complaints procedure in England was the scrapping of Community Health Councils at the end of 2003 (though still operational in Wales), a demise that many regret. CHCs were independent and recognisable health advisory bodies, there to monitor and review the National Health Service and to recommend improvements. They also acted as advocates for patients who had experienced problems with their NHS healthcare. Community Health Councils had the advantage of being based in the community and were seen as truly independent by patients pursuing a complaint against the NHS. They were also often staffed by people with considerable commitment and expertise, providing clarity to what has now become very muddy waters.

AvMA (Action against Medical Accidents) is an independent charity which promotes better patient safety and justice for people who have been affected by a medical accident. Recently, it raised concerns over the future of ICAS which was supposed to replace Community Health Councils' complaints support in England. It was intended that an ICAS was to be provided by the statutory Patients and Public Involvement Forums in each Primary Care Trust area, with standards to be set and monitored by the new Independent Commission for Patient and Public Involvement in Health (CPPIH).

The Government has now announced it will abolish the CPPIH just a year after setting it up. Meanwhile, after a pilot and interim stage of ICAS, three out of the four providers have ceased to guarantee that this specialist support will be available. There are now serious concerns about how ICAS will support complainants with some of the most complex and serious clinical complaints in some parts of the country. According to AvMA, in the East Midlands people mentioning the mere possibility of compensation were directed straight to the personal injury claims department of a local firm of solicitors.

CHCs may be history, but why is a patient's complaint still not taking seriously from the very first call that they make? Why is it up to the patient, as a potentially wronged patient, to hunt around for answers? Patients are confused when they hear that the remit of an organisation is to 'protect patients' but can't do anything about an adverse drug reaction, or that a Patient Advisory Liaison Service won't deal with a complaint about the performance of a doctor. Is it the patient who is wrong? Naturally, I suggest not. Frightened of the consequences of raising their concerns, often angry and feeling vulnerable, patients will be told to contact someone else and as their energy levels diminish so their anger increases.

It is high time that there is one place where patients can voice their concerns when something goes wrong. This one place is with patients, it is wherever they think it is appropriate – either the Patients' Association, the GMC, the Health Commission, another regulator or whomever they choose. It is high time that we all worked closer together and co-operated to deal with the real issue of patients' frustration with the system. I would like to see a single telephone number that all regulators use, including maybe the Healthcare Commission, and maybe even a few patient organisations, so a patient can phone up when something goes wrong knowing their call will be logged, taken seriously and directed to the most appropriate organisation. The emphasis should be on us doing the leg work not the patient. It's in our interests not to lose valuable information about their experiences and to learn from our mistakes.

We do now have an opportunity to move this forward with greater co-operation and co-ordination of the regulators through the Council for Healthcare Regulatory Excellence and with an increasingly influential and effective Healthcare Commission. There is also an opportunity because many patient groups are now involved in the process rather than shouting in from the cold. Many patient groups, despite the usual funding crises we all go through, try our best to recognise the changes and have become more professional to reflect the need for our involvement. This is a two way street, however. If the proper involvement of patients through patient groups is to be effective then our contributions must be recognised accordingly. Patient groups need to provide a service that is professional, and advocacy, however you may define it, does not come cheap. To rely on any patient or patient group involvement must mean they too can rely on some recognition other than the cost of their bus fare home. Similarly when patient groups run helplines we have to rely on volunteers because of the costs of any alternative. While a volunteer run helpline certainly can be professional, the demands for a co-ordinated call centre would obviously need a very different approach.

It is this different approach that is needed. As the saying goes 'if you always do what you've always done, you always get what you always got'. What we have always got has let too many patients down, so we need to do it differently, do it together and do it soon. A unified complaints mechanism would be one step to making this a reality. Remember, every day's delay is 110 avoidable deaths.

## CHANGING THE CULTURE IN PATIENT SAFETY

LORD HUNT OF KINGS HEATH,  
CHAIRMAN, NATIONAL PATIENT SAFETY AGENCY

The National Patient Safety Agency (NPSA) is defined almost as much by what it is *not*, as what it is. It is *not* a regulator and it is *not* part of any disciplinary system. In fact it exists in a parallel universe to the word of regulation, blame and disciplinary action in the health service.

We were established in July 2001 following recommendations by the Chief Medical Officer's reports on patient safety, *An Organisation with a Memory*<sup>10</sup> and *Building a Safer NHS for Patients*.<sup>11</sup> These papers set out the case for the health service to learn from when things go wrong – not just locally but across the whole health service.

Although estimates vary about the extent of the problem, a small study in two acute care trusts in England<sup>12</sup> points to a national picture of 900,000 patient safety incidents a year in UK hospitals, or one in ten patients admitted to an NHS hospital experiencing a patient safety incident where they either come to some degree of harm or are exposed to a risk that could result in compromised treatment. We do not yet have these 'best guess' figures for primary care, the ambulance or mental health services.

For a typical hospital this would mean around 3,000 patient safety incidents a year. More than 1,000 of those incidents will have moderate to severe consequences for patients and many will be devastating to everyone involved. This also inflicts a heavy toll on the resources of the health service, costing well over 27,000 extra bed days and about £7.4 million a year.

The airline industry has been a key safety model for the NPSA – mainly because there is nothing else in the healthcare arena anywhere in the world comparable to what we are doing in the NHS. Those responsible for improving airline safety made two fundamental discoveries which revolutionised the way untoward incidents were approached. First, they found that staff were afraid to admit to mistakes because owning up only brought punishment. Consequently, any learning that could have resulted from thorough and open investigations was lost and the same errors were repeated. Second, they found

that the person who made the error was always the one who carried the can, when it was often a failure of the system in which they worked that ultimately led to the mistake.

The Kennedy Report into the Bristol Royal Infirmary<sup>13</sup> marked the beginnings of a cultural revolution in the NHS, with its recommendation that, "Every effort should be made to create in the NHS an open and non-punitive environment in which it is safe to report and admit sentinel events."

At the NPSA, we aim to replace a blame culture in the NHS where errors are hidden, with an open and fair culture where we learn lessons when things go wrong. We are setting up a National Reporting and Learning System (NRLS) which will capture local reports of patient safety incidents and store the anonymous information so that patterns and trends can be identified and used to point the way to areas where practical solutions are needed.

If we are successful in overturning the blame culture, the NHS will move away from its traditional response to errors and will begin to resemble the airline industry where this open and fair culture is well developed.

A mark of success for this culture change would be to see an increase in the number of reported incidents, but also a fall in the number of high-risk incidents that take place. A rise in reported patient safety problems may be difficult to explain as a barometer of success to a sceptical press and pessimistic public. But until every incident where patient safety is put at risk is recorded, no matter how minor the actual consequences at the time, the health service will not have the opportunity to learn in full the lessons that can make the NHS a safer place. These reports of seemingly minor mishaps can prevent more serious accidents taking place in future. For instance, an incident where a patient is given an aspirin destined for another patient with no adverse consequences, can highlight lapses in the system, which on another occasion, could lead to a patient receiving a potentially fatal drug meant for another patient.

This stance is not opposed to the normal disciplinary checks within NHS trusts. Individual responsibility cannot be abandoned, but we have to separate accountability and blame. A fair and open NHS culture is not a no-blame licence. People who abuse their position or act recklessly should clearly be brought to account and have to face up to accusations of negligent or criminal actions. But when a crisis arises, managers should ensure that they look at the way systems work as well as what actions individuals have taken.

The NPSA aims to work at a national level supporting the work of local clinical risk managers and aggregating their experience and information so

lessons can be learned that can be applied across the whole health service. We are also developing national models of good practice and practical toolkits to help managers arrive at fair and consistent decision-making. For example, running courses on root cause analysis to help health managers take a fair and systematic approach to investigations. This should help to reduce the number of nurses suspended from duty – at great cost to the health service, and help managers to focus on systems failures as well as individual responsibility.

Our role to improve the safety of NHS patients by promoting a culture of reporting patient safety incidents is underpinned by the NRLS. This system, managed by the NPSA, should be receiving reports from all local NHS organisations in England and Wales by the end of the year (December 2004), either through their own local electronic risk management system or electronic reporting forms (eForms) on the web. Eventually all local risk management systems should be linked to the NRLS so that locally filed reports are automatically sent through to the NPSA and submitted to the NRLS once all identifying information has been removed. After local systems are fully integrated with the NRLS all patient safety incidents should be reported to the NPSA through the automated system.

Although the eForm allows health staff to report directly to the NPSA, we encourage staff to allow the Agency to share the information with their home organisation – either with their name attached or anonymously – so local learning can also take place. The accumulated reports sent to the NPSA will be subject to sophisticated statistical analysis. This report will form the basis for identifying trends and will highlight significant patterns of incidents. The first NRLS report will be published at the end of the year (2004). The Agency will be able to provide feedback to local organisations and direct its practical work to avoidable incidents where it can develop solutions that enable NHS organisations to improve systems and procedures.

We would like to see possible problems tackled at their root, so the potential for harm is lessened. This may mean redesigning systems or equipment so it is impossible or very difficult to treat patients in the wrong way.

The NPSA has three levels of urgency for communicating with the health service – alerts, which require prompt action to address high risk safety problems; safer practice notices that strongly advise implementing recommendations; and patient safety information which suggests issues or effective techniques that healthcare staff might consider to enhance safety.

The NPSA has already issued a patient safety alert on standardising crash call telephone numbers, recommending that the crash call number used to summon a specialist team when a patient has a heart attack in a hospital should be the same across the health service (2222) to avoid health staff delaying treatment by calling the wrong number.

It has also issued a safer practice notice on safer ways for hospitals to buy, manage and use infusion devices, used to deliver drugs and painkillers via a drip into the vein. The Medicines and Healthcare Products Regulatory Agency (MHRA) receives over 700 reports of unsafe incidents with infusion devices (including ten deaths) every year. Hospitals were keeping stocks of a wide range of devices on each ward and facing difficulties with providing adequate training for nurses on such a wide variety of infusion devices. The NPSA report recommended that hospitals should standardise the range of devices and set up equipment libraries to maximise the use of devices – a solution that should lead to greater safety for patients, substantial savings in the health service.

The NPSA is also currently working on the mis-matching of patients to treatment. This includes wrong site surgery where the wrong limb is amputated or the wrong kidney removed – because of a failure in communication and checking procedures; cases when patients' blood, tissue samples or specimens are confused leading to wrong diagnosis or treatment; and instances when medicines are given to the wrong patient. The NPSA is looking at the potential for bar-coding, radio-tagging and other technologies, as well as improving traditional manual checking procedures, as ways to avoid these problems in future. Other areas of work include safety on acute psychiatric wards, improved safety for methotrexate, a potent drug normally taken weekly, and intolerance to latex, used in most surgical gloves. We are also trying to highlight effective ways of working. For example, a theatre team in the south-west has adopted the type of team briefing used by airline crews to review performance and procedures, including patient safety, work loads and stress levels.

A ten minute session at the start of a theatre list is conducted by the surgeon or anaesthetist to look at technical aspects of the day's work, discuss the patients on the list and ensure that staff know each other and the roles they will perform. A similar session is held at the end of the day, usually chaired by another member of the team, where issues like cooperation, communication and dispute resolution are examined in a non-judgemental way. One of the primary benefits of these briefings is the ability to look at potential for error at

the start of the session and look at near misses that occurred during it. All theatre staff are given the confidence of knowing exactly what is expected of them, what they can expect of colleagues, and that they are respected and listened to and that they can admit to errors without judgement or censure.

Team working should go beyond clinical teams and involve everyone involved in patient care, especially NHS organisation boards and patients. Improvements in patient safety are more likely to come about if patients are involved in their own care. Patients will assume much greater power in the NHS of the near future. They will have access to good quality information, telling them who is delivering safer care and giving them the power to choose where they are treated. This will enable them to vote with their feet. Patients with greater knowledge will bring benefits and become active partners in their own healthcare. Comprehensive and reliable information will dispel some of the current panic and alarm associated with the ad hoc reporting that occurs when tragic cases hit the newspapers. The NPSA always involves patients in its work as solutions are more robust if they incorporate patients' views and concerns.

For example, some of the blame for the spread of the antibiotic-resistant MRSA in hospitals has been attributed to health staff failing to clean their hands between each patient contact. The NPSA worked with six hospitals to encourage hand washing amongst staff. It tested the effect of placing antiseptic hand cleaning gel at every bedside. The study also used posters as reminders and involved patients by offering staff badges and disposable aprons with the slogan "Clean your hands; It's OK to ask" to encourage patients to question staff caring for them about their hand hygiene.

Initial results from the 'cleanyourhands' campaign show that patients appreciated being responsible for their own care and staff felt comfortable about being asked to wash their hands. Encouragingly, the number of staff cleaning their hands increased significantly over the period of the pilot. With hospital-acquired infections costing the NHS an estimated £1 billion a year, this is a clear illustration of one way in which patients can directly help in the delivery of safer and more cost effective care.

Although it is important to illustrate what sort of improvements the work of the NPSA can bring about to make the NHS a safer place for patients, the biggest and most important task for the NPSA is to work towards a cultural shift that will be apparent throughout the health service. NHS organisations can start their own cultural revolutions to bring about an atmosphere in which

staff feel able to report patient safety incidents and near-misses through using the NPSA and the tools it has developed without, of course compromising normal accountability and disciplinary structures.

Cultural change, if implemented properly, can and will make significant and permanent improvements for both patients and staff.

<sup>10</sup> Department of Health Expert Group (2000)

<sup>11</sup> A Report by the Chief Pharmaceutical Officer 22nd January 2004

<sup>12</sup> Adverse events in British hospitals: preliminary retrospective record review Charles Vincent, Graham Neale, Maria Woloshynowych *BMJ* Volume 322, 3 March 2001

<sup>13</sup> *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 -1995* Command Paper: CM 5207

## PROFESSIONALLY-LED REGULATION IN THE LAW – A COMPARISON

JANET PARASKEVA, CHIEF EXECUTIVE, THE LAW SOCIETY

Regulation of professionals is controversial. In the medical profession the issue came to the fore as a result of some serious problems which publicly damaged the reputation of doctors. For lawyers, the government's determination to tackle what it sees as a regulatory maze in legal services and its concern about the number of complaints about solicitors, resulted in the decision to commission an independent review of legal services and a great debate has followed.

The regulation of doctors and solicitors works in quite different ways. The first and most obvious substantive difference is that while solicitors have one body to regulate *and* represent them, doctors are regulated by one organisation (the GMC) and represented by another (the BMA). In fact regulation of doctors is much more complex even than that, since there is also significant involvement by the Royal Colleges in the regulation of doctors in different specialisms, including general practice.

Regulation of both doctors and solicitors can be described as professionally-led, though the structure of their governing bodies is slightly different. The GMC has recently reformed its Council, reducing it in size from 104 members to 35. Of those 35, 19 are elected medical members and 2 are appointed medical members. The 14 lay members are appointed by the Privy Council following an open appointment process. The Law Society, by contrast has 5 lay members on its Council of 105 individuals. The remaining 100 Council members must be solicitors and are elected by members of the profession.

The work of the GMC is overseen by the Privy Council, the Council for Healthcare Regulatory Excellence and the Charity Commission. Unlike The Law Society, no external approval is required for its equivalent of practice rules. Rules governing the solicitors' profession, however, must be approved either by the Lord Chancellor (now Secretary of State for Constitutional Affairs) or the Master of the Rolls, depending on the purpose of the rule.

In addition to oversight by the Lord Chancellor and the Master of the Rolls, there are a number of other levels of oversight of the regulatory work of The Law Society. The Legal Services Commission sets additional standards for franchised/contracted, publicly-funded legal aid work. The Financial Services Authority (FSA) may regulate the conduct of mainstream investment business work by firms of solicitors which are authorised to do that work while the FSA also supervises The Law Society's regulation of firms carrying out exempt regulated activities.

There is a Legal Services Ombudsman who oversees complaints handling by the legal professions and the Secretary of State for Constitutional Affairs also announced recently the appointment of a Legal Services Complaints Commissioner (LSCC) under the provisions of the Access to Justice Act 1999. The LSCC will be able to set targets for the Society's complaints handling and has the power to impose fines. The work of immigration solicitors is supervised by the Office of the Immigration Services Commissioner.

The GMC is not a general complaints body and can only act where there is evidence that a doctor may not be fit to practise. Issues that do not call into question a doctor's GMC registration can usually be resolved locally, through the NHS procedures. For The Law Society, however, dealing with complaints about service is a major part of its regulatory work, in addition to enforcing practice rules and disciplining those who are in breach of the rules.

Despite these quite substantial differences, it is possible that the current review of regulation of legal services may bring the regulation of the two professions somewhat closer. Headed by Sir David Clementi, Chairman of the Prudential and former Deputy Governor of the Bank of England, the task of the review is to consider what regulatory framework would best promote competition, innovation and the public and consumer interest in an efficient, effective and independent legal sector. As I write, Sir David is in the process of drawing up his report, which is expected at the end of 2004. There has been a public consultation – in which The Law Society played an active part – looking at different models for regulation and complaints handling, as well as the gaps that exist in the current regulatory framework and possible new business structures for delivering legal services to the public.

In recent years there has not been immense change to the regulation of the solicitors' profession – the last major piece of legislation specifically concerning solicitors was the Solicitors Act of 1974. Significant change did come in 1985 when the Society began dealing with consumer complaints for

the first time. And there has, over the years, been considerable discussion of possible changes in the rules and liberalisation of practice which would have required changes to regulation, though not necessarily to its overall framework. These have included decisions in principle to allow multi-disciplinary practice (where solicitors could set up in practice with say, accountants or surveyors) and to allow employed solicitors to deliver legal services to third parties. This is not currently allowed and such a change would mean that, for example, where a solicitor was employed by, say, Boots, he or she could deliver legal advice to customers who paid Boots, not the solicitor, for the service. However, it has not been possible to implement these decisions without legislative change – which has not been forthcoming.

The government, however, has been concerned about what it calls the regulatory maze. It has described the current regulatory structures as “outdated, inflexible, over-complex and insufficiently accountable”. Though The Law Society would argue that these concerns are over-stated, there is no denying the variety of different regulators. Just as ‘the healthcare professions’ means not just doctors, but also nurses, midwives, pharmacists, dentists, opticians and many others, ‘legal services’ embrace not just solicitors, but also barristers, legal executives, patent agents, notaries and licensed conveyancers. Each of these has its own professional body and its own individual approach to regulation – for example barristers are regulated by the Bar Council but the process of qualification also involves the four Inns of Court, while notaries are appointed by the Archbishop of Canterbury and are subject to regulation by the Notaries’ Court of Faculties. Others who deliver legal advice are not regulated at all.

Change has also been prompted by the Office of Fair Trading (OFT), which published a report into competition in the professions in 2001. The OFT was concerned that the limitations on competition in the legal professions imposed by professional rules and legislation, limited choice for the consumer and made lawyers seem less accessible to the public. It was in response, in part, to concerns about the suitability of current structures for delivering legal services that prompted The Law Society Council in the 1990s to begin looking at liberalisation of some practice rules.

On top of these forces for change, there have also been changes in the shape of the profession, which have further highlighted the need for reform of regulation necessary. Numbers in the professions have grown hugely over a past generation. For example, the solicitors’ profession has grown in size by

about 250% since 1970. As professions grow larger, the pressure of collegiality as a control on behaviour diminishes. In a small profession such as, say, the solicitor’s profession in Northern Ireland (approximately 2,500 members) the incidence of complaints is low, as is the incidence of serious misconduct. Solicitors come under pressure from their peers to resolve clients’ problems quickly and the network of intelligence is such that a potential wrongdoing by a solicitor is detected early. The dynamics in a large and diverse profession are different.

The willingness of clients to trust their professionals unquestioningly has also changed radically in recent generations. Members of the public are better educated and have more access to information. They are better able to make informed judgments about the quality of the service they have received if not the degree of expertise. They have ever increasing expectations from solicitors and other professionals on issues such as quality, good customer service and value for money. There is also increased media scrutiny of the professions. Not only do large systemic failures generate huge public attention but also the wrongdoings of individual professionals will make the headlines on any given day.

The current review was the result of these various concerns and shifts in the climate in which legal services are delivered. One of the most important issues being addressed by Sir David Clementi in this review is the kind of structure should be adopted for the regulation of legal services.

David Clementi described two main models, which he calls A and B, plus a third variant, model B+. Model A would entail the removal of all the regulatory functions from all professional bodies (The Law Society, Bar Council, Institute for Legal Executives and others), vesting them in a Legal Services Authority instead. This body would directly regulate the providers of legal services and would be in some respects analogous to the current Financial Services Authority. Sir David suggested in his consultation document that a Legal Services Authority would be responsible for the setting and enforcement of the rules which govern the provision of legal services, providing advice and guidance on general policy and exercising investigative, enforcement and disciplinary powers.

The main alternative to this structure would be to establish an additional layer of regulation in the form of an overarching regulator – which Sir David suggested might be known as the Legal Services Board. This structure – model B – would oversee the regulatory work of the existing professional bodies,



which would continue to exercise their regulatory functions, in more or less the same way that they do now. The Legal Services Board would be responsible for approving the rules and procedures of the professional bodies and Sir David envisages that it might also oversee enforcement of the rules. This model is somewhat analogous to the Council for Healthcare Regulatory Excellence, which acts as a co-ordinating body for the various regulatory bodies in the medical sphere and has the power to examine their disciplinary decisions.

David Clementi's B+ model would operate in the same way as model B, but with the additional stipulation that the regulatory work of the professional body would have to be separated either by clearly ring-fencing it within the existing professional body or by the creation of separate bodies. The B+ model also offers a number of possibilities between the two principal models of A and B, which are at opposite ends of the spectrum.

There are some arguments in favour of the Legal Services Authority model, particularly around consistency of regulation, new business models for delivery of legal services and the need to regulate those advisers who are currently unregulated. It is The Law Society's view, however, that a variation of the Legal Services Board model overseeing the existing regulators would work best. Such a large body as the LSA could become easily bogged down in its task, and become slow and unwieldy. It might also reduce the sense of responsibility and ownership of regulation and professional values felt by professionals, and may lead to an inappropriate degree of government intervention in the workings of the legal professions.

On the other hand, a Legal Services Board could build on the strengths of the existing regulatory structure and help ensure a consistent approach to regulation across the legal professions, without the risk of inappropriate government intervention. It would help maintain professional commitment to the regulatory structure and thus help promote and maintain high standards in the profession. However, careful consideration would have to be given to the question of how proper lay representation would be secured in such a structure.

There are of course disadvantages to this kind of professionally-led regulation as well as advantages, but The Law Society is firmly of the view that the benefits are of far greater importance.

The principal disadvantage of professionally-led regulation is the risk that it might be driven by self-interest – where professionals conduct their work and their businesses in ways that advantage themselves, not their clients or

patients. Even where this is not in fact the case, a perception often develops among members of the public that self-interest is the chief motivating factor.

Research on what the public thinks of The Law Society was done in 2002 and it showed that though some people had a vague recall of the organisation, for most their knowledge was extremely limited. The Society was seen as a solicitors' club and there was little awareness that The Law Society also acted in the consumer interest. Many respondents just assumed that solicitors would simply close ranks in the face of complaints against them.

However much we may disagree with this perspective, it is not difficult to understand how some might reach this view. Self-interest is a motivating factor on so many levels in human activity and relationships. We should not be surprised that those outside the professions might conclude that where professionals are responsible for regulating themselves they might take an approach that systematically favours the professional over the client, consumer or patient.

If self-interest is a reality then it will discredit professionally-led regulation. However, it is The Law Society's firm view that great benefits come from professional involvement in regulation and that it is entirely possible to guard against the risk of corruption of the system.

There is real merit in professionals being involved in their own regulation – the concept of professionalism still has great value for society. Being a member of a profession regulated by a professional body confers on the practitioner different expectations (in their own eyes and those of society) from those expected of someone who merely provides services in accordance with statutory rules regarding consumer protection and competition.

Belonging to a professional body means subscribing to an ideal, not just obeying rules imposed from without. As a result, solicitors recognise that Law Society rules are a real expression of what professional conduct should be. The benefit of this to society is that they can trust the vast majority of those who describe themselves as professionals. The public can rely on the vast majority of solicitors to be largely self-policing because they are motivated by an inherent ethical commitment, rather than simply abiding by the minimum level of compliance to stay within the rules set by an external regulator. Independence and a commitment to the core principles of putting the client first, protecting client confidentiality and avoiding conflicts of interest are at the heart of what is to be a solicitor. Clearly these principles should be preserved in any new regulatory arrangements.

Any proposed change to the rules that govern the profession prompts passionate debate, and this is an indication of the strength and vigour of solicitors' professionalism. It is our firm view that this sense of professionalism is best promoted by solicitors having ownership of the responsibility for how they and their peers behave, and strong involvement in setting the standards and judging how they are met.

To head off consumer concerns – however ill-founded – that the regulator might choose to act in the interest of the profession, it will be essential that at every level there is a substantial independent element. Ideally this should mean a balance between lay and professional members, both on any oversight body and within the regulator itself.

The recent debate about regulation among solicitors has been lively and impassioned and it has been impressive to see how much many solicitors really care about how their profession works. It seems to me that regulation for all professionals is going through a period of great change as accountability and transparency join with effectiveness as key tests of the performance of a regulator. That this is the case reflects the passing of a society where deference prevails, and that can only be a good thing. Everyone in society – not just the privileged few – is entitled to excellent advice and services from professionals. I hope that in legal services we will be able to secure that through reforms to regulation that are imaginative and constructive, respecting both the contribution of the professional and the rights of the consumer.

## THE REGULATORY ENVIRONMENT IN THE UK AND EU

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In the United States, some have estimated that regulation may account for 10% of GDP, with compliance costs alone adding up to 2.5%. Those figures are unlikely to be radically different in any of the major EU Member States. The Better Regulation Task Force has provided a broad definition of regulation as "any measure or intervention that seeks to change the behaviour of individuals or groups". It illustrates this definition by going on to say "it can both give people rights (e.g. equal opportunities) and restrict their behaviour (e.g. compulsory seat belts)." There is little need to argue with that as a public interest justification: it is when questions of application come into play that problems arise. This chapter assesses recent developments in UK and EU regulatory structures and assesses standards of application against best practice principles: what can and should be done to constrain those costs; does the process operate transparently and accountably; and do public and private sector regulators operate within a responsible culture?

The seven years since Labour took power have seen much activity in the regulatory policy area. New scrutiny bodies such as the Better Regulation Task Force (BRTF) and the Panel For Regulatory Accountability have been established. The National Audit Office has been given responsibility for sampling and checking a limited number of Regulatory Impact Assessments. The Regulatory Impact Assessment rules (in reality legally unenforceable administrative requirements) on cost-benefit analysis have been regularly refined and strengthened, now applying to all departments, public bodies and sector regulators. Regulators, while appointed by Ministers, now have to report to non-executive boards, which have also been introduced to Whitehall ministries. Departments now have Better Regulation Ministers and officials and board-level "champions", and the Regulatory Reform Act offers the scope to scrap or amend outdated measures without the need for primary legislation.

Brussels has also produced a raft of regulatory process reviews,

programmes and requirements. In 2002 the Commission published its Action Plan on Better Regulation, with a large number of proposals for improving the way Community institutions and Member States consult on policy proposals and assess their impacts. In particular, it extended to the Council, European Parliament and to Member States the requirement to submit draft measures to assessment of economic, social and environmental impacts. In parallel, an Inter-Institutional Agreement signed last year includes a commitment to develop a fast track simplification procedure. A common theme for the three European Presidencies to the end of 2005 will be better regulation.

Good news then? Perhaps not yet, because although Brussels and Member States have not lacked for better regulation or evidence-based decision making programmes in recent years, their practical application still leaves much to be desired. Surveys (most recently by the SMF between 2002 and 2004, covering major UK companies and representative bodies<sup>14</sup>) consistently reveal four main concerns among regulated sectors.

The first was a strong suspicion that policy decisions are in many cases initiated before the system has fully examined the evidence that should inform them. Consequently, outsiders feel that evidence is as often tailored to suit political drivers as it is used to guide decisions. This is sometimes because of the need to be seen to act: handguns and dangerous dogs are prime examples. Look also at what happened in the wake of Enron, when Europe's politicians and the Commission pressed for a range of new regulations from corporate governance to trading in derivatives without undertaking impact assessment. One example was not checking whether forcing derivatives trading onto regulated markets would inhibit the development of an efficient capital market in Europe through handicapping the growth of a variety of trading platforms. This phenomenon applies equally to self-regulated sectors as to statutory regulation.

Associated with this, the regulated do not believe that Whitehall or Brussels are truly committed to better or streamlined regulation (we have avoided mention of less regulation: as we will argue below, it is too easy to confuse volume and detail with gold plating); if it is, there is a widespread coyness about publicising cases where an evidence-based decision making approach has made a difference or where alternatives – self or co-regulation (or even the status quo) – have been adopted in preference to formal regulation. An assessment of the annual reports of the 12 leading "regulatory" departments in August 2004 revealed that while most had complied with the

Treasury's requirement to list examples of alternatives having been pursued, very few instances were offered. In Europe, successive summits have for several years committed the Union to improving the regulatory environment, but the Lisbon commitments appear only to be paid lip service.

One of the most frequently cited examples of this apparent mismatch between words and actions is the UK's Panel for Regulatory Accountability. This is a mechanism which enables the Cabinet Office to question departments on their compliance with better regulation principles. It meets behind closed doors under the chairmanship of the Prime Minister. No outsider is told of the agenda, input from outside Whitehall is not welcomed, no reports are issued on the outcome of meetings and there is no apparent action. It may in reality achieve much, but good regulatory practice has to be demonstrated, not taken on trust.

The third problem is the scope for political vagaries to intrude into essentially technical decisions. The confidence of stakeholders in a "reasonable expectations" approach (see below) can be destroyed by a political overlay to the policy process that does not appear to be founded on sound evidence. "We think we bend over backwards to get the science right", one regulator commented to us, "but our relationship with the industry sags every time Ministers choose to ignore scientific advice drawn from sources we and those companies respect." Limiting the uncertainty caused by vague decision making timetables was frequently raised. As Ofwat Director General Philip Fletcher said to the Environmental Audit Select Committee in commenting on the impact of Defra's delay in reaching a decision on the water pricing review on his published timetable, "The key issue for which we are all waiting is the ministerial guidance. It is a bit like the Secretary of State saying "Godot must be round the corner soon".<sup>15</sup>

Lastly, there is confusion over where regulatory independence ends and political influence begins. Regulators are formally independent but in some respects are still beholden to Ministers (for example the water pricing review cited above). They are also subject to guidance handed down from departments. The Utilities Review 1998 led to the establishment of an additional process through which regulatory objectives may reflect government policy objectives. The review led to subsequent legislation introducing a duty on the energy and postal regulators to have regard to governmental guidance on social and environmental objectives and the Water Act imposes similar obligations on Ofwat. Given that economic regulators may

also have a statutory duty to ensure that return on capital is sufficient to cover infrastructure investment needs, this can lead to a confusing politically-imposed balancing act between criteria.

The problem is part technical, but mostly cultural. Few accountability requirements placed on UK or Community institutions are statutory, and therefore legally enforceable. If policymakers fudge data or reach decisions without properly assessing the balance of costs and benefits, in most cases Judicial Review is unavailable. In parallel, the right of appeal against regulatory decisions is inconsistent: it only exists where Parliament provides for it. Incorporation of the European Convention of Human Rights into UK law has had direct and indirect effects. Recent legislation, such as the Communications Act 2003, incorporates European Directives which pay full regard to the philosophy of appeals being made on the merits of the case, and with those appeals being heard by independent tribunals.

Nor have either the UK or European parliaments shown any great desire to undertake systematic parliamentary scrutiny of the regulatory process. In the UK, the Public Administration Select Committee has demonstrated little interest in this area and European Parliament Committees have rarely probed the governance underpinning Commission or Council proposals. The Lords Constitution Committee, in a lengthy report on regulatory accountability observed that "Scrutiny at the moment is dependent on individual committees deciding that inquiry is necessary into a particular regulator or regulatory decision. It is thus both fragmented and inconsistent. There is no means of establishing a coherent overview of the regulatory regime."<sup>16</sup>

However, the increasing use of joint committees of both Houses to undertake pre-legislative scrutiny has made a noticeable difference, for example by strengthening the Communications Bill (now the 2003 Act) to include a statutory Regulatory Impact Assessment requirement and an obligation regularly to review and remove any regulations that are unnecessarily burdensome or superfluous. The committees' open hearing structure has inspired confidence in the joint scrutiny process, a lesson departments and regulators have not yet learnt.

The incentive thus exists for Governments and sector regulators to view the Better Regulation agenda as an à la carte menu, either doing the bare minimum of work necessary to produce an impact assessment or selecting convenient evidence to support decisions, in both cases banking on being able to resist any subsequent objections. While there are many examples of

painstaking research and consultation, the Commission itself has acknowledged that the June 2002 package was designed to address a widespread mindset among policy makers that led to Business Impact Assessment forms being completed with nothing more than guesswork as the last action before presenting a draft proposal to Commissioners. However, major regulatory proposals (for example, the Council's passenger information Directive) are still being driven through without an impact assessment. In the UK, the instances of RIAs not being produced at all are dwindling as a consequence of the Regulatory Impact Unit's oversight. However, quality is often poor and, as several officials have acknowledged to us, too often the process is undertaken half-heartedly and with an eye to a conclusion already reached. The process of signing off an impact assessment at ministerial level is frequently just as dismissive.<sup>17</sup>

A contributor to the concerns expressed by business is, however, business itself. Officials point out – with considerable justification – that poorly evidenced conclusions stem from the poor quality of responses they often receive from companies or from professional and trade bodies handicapped by having to work at lowest common denominator level. And outside organisations have generally been slow to call the system to account for failure to follow good regulatory governance principles. The mechanisms in place – impact assessment and the BRTF in particular – that can call the system to account are only likely to succeed in improving the quality of the regulatory process if consultees supply better data and keep the system on its toes.

Performance on both sides may improve when a legal sanction is involved. The Food Standards Agency is an example to note. Because it is one of the few regulatory bodies to be statutorily required to demonstrate that proposals are justified on the basis of cost-benefit analysis, it takes great pains to set out its evidence in order to avoid Judicial Review, with the result that it is rarely challenged. The UK Government and the Commission have nonetheless rejected suggestions that wider legal accountability should be built into public administrative and policy processes.

By way of comparison, accountability mechanisms are rather more advanced in the United States. A 'Truth in Regulation Act' was passed in 2000 authorising the General Accounting Office to conduct a pilot programme of independent reviews of economically significant rules proposed by government agencies. In practice the pilot programme was not funded but in the meantime the Office of Management and Budget (OMB) has moved to establish the same principles in a

different way. In September 2001 OMB announced new science based 'principles and procedures' for evaluating regulatory proposals put forward by government agencies, including independent peer review procedures for impact and risk assessments to establish a presumption of objectivity. In addition, OMB is implementing a standard of 'capable of being substantially reproduced' with the aim not so much of error correction as of better public understanding of the basis on which a rule or regulation is proposed.

Although, as has been said, those who are regulated have not always taken the opportunity to call the system to account, business and individuals are more aware of regulation, and that has led to a perception that burdens have increased and that the system as a whole operates in a malign manner, seeking to pump out regulation without regard to its impact on the regulated. The red tape lobby has prompted many deregulation initiatives, the most prominent of which are the Regulatory Reform Action Plan (RRAP) in the UK and the EU's SLIM programme. SLIM has set a target of some 25,000 pages being removed from the statute book as overlapping or superceded measures are reviewed and culled. 300 RRAP items are under way and other developments have included the setting of common twice-yearly commencement dates for all employment requirements. But as the Better Regulation Task Force has pointed out, "Ministers do much more regulating than deregulating. The Government may have hoped that Ministers would naturally want to deliver what are, after all, published commitments to reform, but it seems that some Ministers need stronger incentives."<sup>18</sup> Other tools such as Regulatory Reform Orders have only picked at items, constrained both by the reluctance of organisations to volunteer specific candidates and the limited capacity of the parliamentary committees that review them.

Furthermore, the lobby has often given the appearance of being ill-defined, confused and perhaps self-fuelling. An example of this is the regular concern expressed in the UK about "gold plating" in the transposition of EU legislation. Recent studies have expressed concern that nine page directives have been turned into ninety page statutes by apparently over-zealous British bureaucrats and that other Member States adopt a much slimmer approach. But what some see as gold plating can be welcomed by others as offering greater clarity – short-regulations may create the need for bulky guidance notes. The process of implementing new directives may also offer the scope to consolidate several existing but overlapping measures, adding length but also, arguably, simplicity.

This chapter has largely been critical of shortcomings in the regulatory process. Mostly, however, professional and public sector regulation operates conscientiously and efficiently. If outsiders suspect poor practice, and our own consultations have found that a high proportion do, it is because policy-makers and regulators forget (or cannot be bothered) to show that the process does work and fail sufficiently to engage affected sectors. The best practice lessons in that respect, whether for Whitehall and public bodies, economic and professional regulators or Brussels, are both simple and intuitive:

- Secure buy-in at the outset to the approach that should be taken to addressing regulatory issues. The practice of several of the economic regulators of producing and consulting on "approach documents" before major reviews or other policy exercises has been widely praised. Similarly, the assembly of joint regulator/sector expert "test panels" at the outset can jointly determine whether formal, self- or no-regulation is the right course and agree the most appropriate methodology for assessing impacts of regulatory options, reducing the likelihood of subsequent complaint about decisions.
- Associated with the approach document principle, develop a culture in which uncertainty is reduced through the creation of "reasonable expectations" that also bind successor regulators. It might be suggested that this is no different than at present when, for example, bodies such as Ofcom seek to establish a five year policy framework for telecommunications, and that perfect foresight of market or professional developments is impossible. But a presumption at the outset of the process that regulators and consultees should assess the feasibility of developing "one time, last time" solutions would seem sensible.
- Demonstrate that the proportionality test (i.e. that assessed burdens are proportionate to claimed benefits of proposals) has been satisfied. That means not just reaching conclusions but explaining how they were reached. A recent example of this was the DTI's announcement that it had rejected the option of formal licensing of estate agents in favour of a self-regulatory

alternative because the costs the former would impose were considered unnecessarily high.

- Adopt sector regulators' practice of setting out (and sticking to) timetables for decision-making processes. E.g. production of an approach document, consultation on it, publication of/consultation on draft proposal, initial conclusions, and so on.
- Extend outreach to as many regulated bodies or individuals as possible by establishing an automatic email notification system for regulatory and other information. This reduces the risk that people will claim they were unaware of new requirements and increases the number of respondents to consultation.

Looked at in this way, better regulatory governance can be achieved without significant additional resource or undue delay.

<sup>14</sup> *Accountable Government (Reasonably simple actions Whitehall, Parliament and Brussels could do to promote transparency and accessibility)* SMF Business Forum, Regulatory Best Practice Group, October 2003

<sup>15</sup> Environmental Audit Select Committee 3/3/04

<sup>16</sup> *The Regulatory State: Ensuring its Accountability* 6th Report, May 6th 2004

<sup>17</sup> One Special Adviser admitted to us that "It would not be far off the truth to say that [my Minister] would hardly remember having seen [an RIA]. They have never made any difference to our work – we've got commitments to discharge and we're not going to let this procedure get in our way."

<sup>18</sup> *The Challenge of Culture Change: Raising the Stakes* Better Regulation Task Force 2004