PART 11
BUSINESS REGULATION

Question 11-1: To what extent does regulation in a commercial context make a difference to how the regulators approach the task of professional regulation and does the law provide adequately for professional regulation in a commercial context?

11.1 A majority felt that regulation in a commercial context makes no difference to the task of professional regulation,[1] and opinion was divided over whether the law provides adequately for professional regulation in a commercial context.[2]

11.2 The General Medical Council argued that:

> Regulation within the independent (as distinct from NHS) sector does not, and should not, require a fundamentally different approach or the application of different standards. A regulator will, inevitably, need to adjust the way it implements standards to reflect the different context in which independent healthcare is practised. For example there are areas of practice that may be much more closely regulated than others or where the registrant may work on their own as opposed to being surrounded by colleagues. This argues for legislation which is focused on high level principles, duties and powers and allows the regulator to adapt its methodology according to the context.

11.3 The Health and Care Professions Council agreed that its task was not significantly different in a commercial context. It thought that:

> All regulators in performing their roles need to be alert to the contexts in which practitioners work. This might affect, for example, any requirements the regulators set for continuing professional development or revalidation.

11.4 The Association of Clinical Biochemistry said that the "commercial context of the regulator is irrelevant".

11.5 The General Dental Council, together with several others, drew a distinction between the regulation of individuals in a commercial context, and the regulation of businesses. It said:

[1] Of the 192 submissions which were received, 23 expressed a view on this question: 15 said that regulation in a commercial context makes no difference, 8 said that the commercial context does make a difference.

[2] Of the 192 submissions which were received, 16 expressed a view on this question: 7 said that the law was adequate, 5 said the legal framework needs to be updated, whilst 4 said that the current system over-regulates in the commercial context

> The General Dental Council believes that the regulation of professionals is not dependent on the business model in which they work. However, the General Dental Council would wish to take the opportunity of the new legal framework to explore the potential for regulating dental entities (the teams within practices/businesses, irrespective of the business model) as an adjunct or alternative to regulation of individuals, in the interests of greater public protection.

11.6 The General Pharmaceutical Council argued that it is not a business regulator but instead regulates the services provided by registered pharmacies many of whom operate in a commercial setting. Therefore, while financial pressures are a "relevant factor", the key factor was "the provision of patient care".

11.7 The Patients Association expressed similar views. It said:

> Pharmacists working for Sainsbury's or a private dentist working for the Harley Street Group should still be under the same rules, duties and oversight as those working in the public sector. We grant that certain procedures and apparatus may need to be different in order to work effectively in a commercial setting but materially, regulation should remain the same.

11.8 However, NHS Education for Scotland considered that the "commercial context makes for a more complex regulatory environment". The Royal Pharmaceutical Society of Great Britain said:

> We believe that regulation within a commercial setting does make a difference. The individual professional is often not in a position of genuine authority or influence and, therefore, is unable to affect decisions made in relation to systems and processes established within the commercial setting. In pharmacy this is particularly apparent with the recent establishment of the responsible pharmacist role, whereby the responsible pharmacist is taking responsibility for an environment they may not be in a position of influence to change.

11.9 The Society of Chiropodists and Podiatrists argued that regulatory decisions need to have a much closer regard to proportionality in a commercial context. It said that:

> Podiatrists and other health professionals in private practice provide a valuable service to the public and must not be placed in a situation where their businesses are not viable.

11.10 The General Osteopathic Council pointed out that its registrants work predominantly in private practice and there has been "intense scrutiny" of advertising and promotion issues, and the sales of various items to patients.

> This is a good example of an area where the duty of regulators should go beyond "safe and effective practice" and hence a broader duty to "maintain confidence" is required.

11.11 The General Optical Council acknowledged that "the commercial context of service provision may make some difference to the work of professionals and the task of regulators". In terms of the effectiveness of the current legal framework, the Council said:

> Where businesses are registered with the General Optical Council, we can and do take action where it is identified that a business has breached our standards. At the extremes, however, the effectiveness of General Optical Council sanctions can be limited in an environment where businesses could restructure to avoid registration requirements, and continue operating.

11.12 The Scottish Government stated:

> The statute should include additional provisions to take account of commercial issues that arise and pertain specifically to the exercise of private healthcare practice, for example financial management and probity, marketing and advertising, and anti-competitive behaviour. This would take account of the fees that are charged to patients in a private capacity (eg dentistry, medicine and chiropractic medicine) and those that arise in the commercial setting (eg optometry/opticians).

11.13 The Department of Health, Social Services and Public Safety for Northern Ireland argued that:

> Regulators need to take into account effects on business and delivery of professional services. There needs to be some test of reasonableness both on the regulator and the recipient, the latter who would probably desire minimum regulation.

11.14 The Professional Standards Authority raised specific concerns about whistle-blowing in commercial contexts, commenting that:

> In some instances there may be pressure to contain cases of poor conduct or performance "in-house" rather than to expose their organisation to public scrutiny and reputational damage as a result of a referral to a regulator.

11.15 Several consultees pointed out that other bodies (including the Care Quality Commission and Monitor) also have regulatory functions in respect of commercial providers of health care, and argued that the functions and roles of all regulators should not overlap. For example, the UK-wide Nursing and Midwifery Council Lead Midwives for Education group pointed out that the Nursing and Midwifery Council has powers to inspect a midwife's equipment and any premises to ensure that safe and effective care can be provided. The British Dental Association was concerned that dentists "suffer from over-regulation" by bodies such as the General Dental Council, the NHS and the Care Quality Commission.

Provisional Proposal 11-2: The statute should retain the existing premises regulation regimes of both the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland.

11.16 The vast majority agreed that the statute should retain the existing premises regulation regimes of both the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland.[3]

11.17 The General Pharmaceutical Council stated:

> We do see the current legislative framework and powers in relation to registered pharmacies as helpful in supporting patient protection and in enabling us to focus on compliance with standards at an organisational level, rather than purely issues of individuals' fitness to practise.

11.18 The Pharmaceutical Society of Northern Ireland felt that in respect of its own legal framework, "the accountability for pharmacists is well defined, clear and firmly established".

11.19 The Professional Leads for Allied Health Professions, Medics, Pharmacy and Psychological Therapies for South Staffordshire and Shropshire NHS Foundation Trust supported the retention of existing premises regulation as "retail issues can decrease public confidence in professions".

11.20 The British Pharmaceutical Students' Association supported the proposal, and suggested that any changes should be consulted upon.

11.21 The Department of Health agreed that the existing premises regulation regimes should be retained in the statute. It also noted "the review of penalties and sanctions flowing from the medicines legislation". However, the Department of Health, Social Services and Public Safety for Northern Ireland suggested that there needs to be reform.

Question 11-3: Are any further reforms needed to the premises regulation regimes of the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland?

11.22 A small majority felt that further reform of the premises regulation regimes was needed.[4]

11.23 The Professional Standards Authority pointed to the need to:

> ensure that business owners, who may by virtue of their position be able to exercise managerial control over registered professionals, are fit people to do so. The position of a pharmacy owner might also bring them into contact with vulnerable people, personal health information,

[3] Of the 192 submissions which were received, 15 expressed a view on this proposal: 14 agreed, whilst 1 held an equivocal position.

[4] Of the 192 submissions which were received, 15 expressed a view on this question: 6 said that no further reforms were needed, 8 said that further reforms were needed, whilst 1 held an equivocal position.

and prescription only medicines. Although we are aware of the standards that apply, we wonder whether there might also be benefit in some sort of "good character" test for people in this position.

11.24 The Authority also argued that sanctions or fines should be disclosed by a business to its shareholders. In addition, it restated its view that "a single UK pharmacy regulator would be desirable".

11.25 The Scottish Government supported the proposal to retain the legal framework of the General Pharmaceutical Council. It also suggested the following reforms:

(1) the regulators should be required to disclose any sanction, condition or financial penalty/notice issued against the business to the shareholders;

(2) the regulator should ensure that any sanctions, conditions or notices applied are complied with and that an enforcement process is in place in the event of non-compliance;

(3) the establishment of a business fitness to practise regime (along the lines of the General Optical Council model) which would allow the regulators to investigate allegations against those who are responsible for businesses that have failed to meet established standards and failed to comply with improvement notices; and

(4) more explicit requirements surrounding the supply of unlicensed herbal medicines.

11.26 An individual consultee (Peter Hopley) argued that the General Pharmaceutical Council's remit should be extended to patients receiving medicines from a dispensing doctor, which currently comes under the NHS primary care organisations through their Dispensing Services Quality Scheme. The Royal Pharmaceutical Society of Great Britain also described this situation as an "anomaly" since different regulatory standards apply, and suggested it should be addressed as part of our consultation.

11.27 The British Pharmaceutical Students' Association suggested that there was a "need for more focus on the provision of education and training" in registered pharmacies.

11.28 The Pharmaceutical Society of Northern Ireland felt that under its regime "the accountability for a body corporate is less well defined" and there should be "greater accountability to the board and directors of companies".

11.29 The Professional Forum of the Pharmaceutical Society of Northern Ireland argued for an extension of the regulators' powers "to ensure that pharmacists are not held solely liable for business failures which may have occurred due to the actions or directions of others".

11.30 The Department of Health, Social Services and Public Safety for Northern Ireland suggested there needs to be a "differentiation of medicines regulation from professional regulation". It also called for provisions "to enable non-pharmacist owners of pharmacy premises to be held to account".

11.31 However, the General Pharmaceutical Council said:

> It is too early in our establishment and our regulatory policy development for regulation of registered pharmacies to state definitely whether the law is adequate. However, we have not yet encountered any limitations in the legislation which we would need to review urgently, although the need to have our standards translated into Rules with Privy Council [approval] has a significant impact on the timeframe for bringing in the full range of powers provided to us.

11.32 A number of consultees did not think that any further reforms should be considered until the conclusion of the Council's consultation on draft standards for registered pharmacies.

Question 11-4: Should the statute retain the existing systems for the regulation of bodies corporate?

11.33 The vast majority agreed that the existing systems should be retained.[5] For example, the Medical Defence Union said that "its experience with the General Dental Council suggests this can work". The British Society of Hearing Aid Audiologists thought the current systems should be retained as "corporate regulation is established and necessary". The Department of Health agreed that the regulation of bodies corporate provisions should be retained.

11.34 The Medical Protection Society was also in favour of retaining the existing systems. It said:

> In our view, the principles behind the existing systems for the regulation of bodies corporate are sound as they permit the public to raise concerns not only about an individual's fitness to practise, but also to raise concerns about the conduct of bodies corporate, for example in the way they deal with complaints or concerns about individual registrants.

11.35 The Scottish Government agreed that the provisions must be retained, but also stated that:

> the new statute should go further in extending the requirement to register businesses to all individual high street outlets and thereby address the confusion that currently exists for both registrants and members of the public. The statute could also make provision for a more proactive system to monitor compliance with business standards. This would provide a more even-handed, consistent and transparent approach and serve to increase public faith and

[5] Of the 192 submissions which were received, 20 expressed a view on this question: 18 said that the statute should retain the existing systems, 1 disagreed, whilst 1 held an equivocal position

> confidence. A model that encompasses the existing systems of the General Optical Council and the General Dental Council and the issues raised above would seem to be a reasonable starting point.

11.36 The General Optical Council supported retaining its system but was interested to explore a new model of regulation:

> that is based on the regulation of all providers of the services protected under the legislation, regardless of their business structure (with the possible exception of sole traders who are already individual professional registrants, to avoid unnecessary dual registrations).

11.37 It noted that significant parts of the business sector are not subject to its system of regulation, and suggested that "all commercial providers of primary ophthalmic services are subject to the same regulatory framework". The Council also argued that it lacked powers available to other systems regulators, and the financial penalties available "are modest relative to the turnover of a large corporation".

11.38 An individual consultee (Dr Susan Blakeney) suggested there is an anomaly that "a body corporate which uses a protected title must be registered" with the General Optical Council "but a partnership which uses such a title cannot be". She further argued that the Council be given powers to decide "whether it is the *activity* that the business conducts that should be registered" and not the title.[6]

11.39 The Pharmaceutical Society of Northern Ireland said that the statute should "go further in defining corporate governance and accountability of bodies corporate".

11.40 The Professional Standards Authority argued that "a fitness to practise regime does not sit well with a registration scheme for bodies corporate". It thought that:

> A more easily understood and appropriate concept in this context might be "fitness for business". A broader application of the concept might be useful, anticipating the potential in future for a wider range of health services to be provided from single premises in a multidisciplinary setting, possibly with an owner who is not a registered professional in any of the areas of service being offered. From the perspective of the public, they would need to know that they were being treated by the relevant professional and not a professional in another discipline or a non-clinical professional.

11.41 The General Dental Council felt that some of its current provisions required further clarification (such as the letter of non-objection) and called for a review "of the purpose and effectiveness of the responsibility regarding names". Some names are currently covered by the Dentists Act 1984 and others by the Companies Act 2006, which the Council felt was a "source of confusion". It also stated that it wanted to "explore the potential for regulating dental entities (the teams within practices/businesses), irrespective of the business model".

[6] Emphasis in the original.

11.42 The British Dental Association felt that the General Dental Council should be able to regulate large businesses such as bodies corporate owning chains of practices. It noted that:

> Currently, the General Dental Council can hold to account the dental directors of these chains, and we consider it essential that the majority of directors of a dental company should be dentists (or dental care professionals). The General Dental Council has not exercised its power very extensively, however, in spite of there being concerns about the influence of bodies corporate on the practice of professionals working for them, and it should take a broader view of its role in this regard. The previous requirement on the General Dental Council to list dental bodies corporate should be reinstated but as a requirement for registration.

Question 11-5: Should the regulators have powers to finance or establish a complaints service?

11.43 Opinion was divided amongst consultees on this question, although most disagreed that the regulators should have such powers.[7] For example, the Health and Care Professions Council argued that "the role of professional regulation is to protect the public, not to provide general resolution to consumer complaints". The Medical Defence Union had "misgivings about the potential for cross-contamination between the General Dental Council's complaints procedures and its fitness to practise functions".

11.44 The Professional Forum of the Pharmaceutical Society of Northern Ireland argued that "every business should be required to have a complaints procedure and that this should be separate from any regulatory process".

11.45 The Royal Pharmaceutical Society of Great Britain stated that:

> Dealing with consumer complaints would cloud professional regulation and have the potential for the regulator to become embroiled in financial redress rather than upholding public safety.

11.46 The Department of Health did not consider that the regulators should have a consumer complaints function since "this could detract from their core purpose". The Northern Ireland Practice and Education Council for Nursing and Midwifery agreed that any involvement in a complaints service "would sit outside the core role of the regulator". For this reason, an individual consultee (Anonymous) suggested that if regulators are to finance or establish services, "it should only be where there is not one already".

[7] Of the 192 submissions which were received, 37 expressed a view on this question: 15 said the regulators should have powers, 18 disagreed, whilst 4 held equivocal positions.

11.47 However, several consultees felt the regulators should have such powers. An individual consultee (James Kellock) pointed out that consumer complaints and professional conduct can be "inextricably intertwined, for example a complaint that an optician supplied defective glasses might involve both". Similarly, the General Osteopathic Council stated it had no desire to fund or establish a separate consumer complaints service, but recognised "it is not always clear where the boundary is between a complaint and a fitness to practise matter".

11.48 The Professional Standards Authority argued that for regulators of registrants that "work outside a well-developed governance framework", such as those who work alone in single-handed practice, "a funded but organisationally separate complaints service could provide a useful mechanism".

11.49 The Scottish Government also felt that the regulators should be able to fund a service that is run by another, independent organisation. It also stated that:

> One option would be for all the regulators to contribute to the funding of one consumer health complaints service. This could provide economies of scale, reduce human and administrative costs and provide an opportunity for shared learning and the sharing of good practice based on customer feedback and complaints received. However, caution would need to be exercised to avoid the potential for duplication of existing forms of redress (eg the NHS complaints system).

11.50 Rescare agreed with the proposed powers in respect of complaints services as long as "such a service is independent of the regulators".

11.51 The General Optical Council stated:

> We believe that there is value for the regulator, registrants and for the public in having a mediation service in place where the sector is highly commercialised. For the regulator, it provides a clear avenue for directing complaints regarding poor products or services but not regarding fitness to practise. This helps minimise the number of minor complaints that regulators deal with and provides a way of helping satisfy complainants that their concern can be dealt with quickly and effectively. The work of the Optical Consumer Complaints Service can also be a useful contributor to our own work in setting standards and producing guidance for registrants on good practice.

11.52 It was also suggested that "regulators may in future want to share resources on such a service, and the statute should allow for that possibility".

11.53 The Optical Consumer Complaints Service argued that:

> There are adequate provisions in consumer law for contracting parties seeking a solution in a dispute, but mediation is an easier option than to resort to formal action. An independent service that can investigate a dispute and discuss a solution with the parties is an expedient means of dealing with consumer complaints. It is of particular value if the service, although independent, is close enough to the regulatory body to be aware of the standards expected of the

> professional's practice and be in a position to alert the regulatory body of any issue coming within its remit.

11.54 The General Dental Council supported the retention of its power to fund and manage the Dental Complaints Service since "not only does it resolve complaints but learning is fed back into the Council's other functions such as fitness to practise processes and setting standards". It was suggested that such a service is necessary because in respect of private patients the Council is reliant on patient complaints "since it does not have a general power of inspection of dental premises".

11.55 The Department of Health, Social Services and Public Safety for Northern Ireland queried if this work should be "resourced through the normal fee mechanism".

Provisional Proposal 11-6: The Government should be given a regulation-making power to extend to any regulator the powers given to the General Pharmaceutical Council or the General Optical Council to regulate businesses.

11.56 A majority agreed with this proposal.[8] For example, the General Optical Council agreed that the statute should make provision for the extension of the power. It said that "given the potential impact of changes to regulatory approaches in this area, we agree that it should be for the Government to extend these powers to regulators".

11.57 The Guild of Healthcare Pharmacists stated that:

> All regulators should ... have the powers to set enforceable standards for owners and those undertaking or managing the healthcare environment that can provide support to registrants to maintain safe and effective practice. The public inquiry conducted by Mr Robert Francis QC into Mid Staffordshire NHS Foundation Trust is likely to raise issues in this area and professional regulation and the support of professionals working within an institution where patient care was routinely neglected by a Trust that was preoccupied with cost cutting, targets and processes and one which lost sight of its fundamental responsibility to provide safe care. Shortages of staff and a culture of bullying those professionals who raised concerns were key factors in creating that unsafe healthcare environment.

11.58 The General Dental Council also supported the proposal on the basis that:

> Regulation of the individual registrant was appropriate for the model of sole practitioners or small partnerships but in today's more complex environment patient safety would be better served by a more wide-ranging approach. Whilst existing arrangements include memoranda of understanding with premises regulators, we would like the opportunity to explore alternative models.

[8] Of the 192 submissions which were received, 25 expressed a view on this proposal: 15 agreed, 4 disagreed, whilst 6 held equivocal positions.

11.59 The Care Quality Commission agreed with the proposal since:

> This would mean that the issue could be considered on the basis of the risk and then the most appropriate regulatory body would regulate. For example, this could be appropriate for a GP whose legal entity is required to be registered with the Care Quality Commission and who is also required as an individual to be registered with the General Medical Council.

11.60 The Osteopathic Alliance considered that any extension of the power to regulate businesses should be limited to circumstances "where it can be shown to be necessary for public protection".

11.61 The General Osteopathic Council supported the proposal on the basis that in the future the regulation of osteopathic practices might be a more proportionate approach than regulation by the Care Quality Commission.

11.62 Pharmacy Voice expressed concern about individual GPs or practices that "adversely influence patient behaviour, for example by directly or indirectly suggesting patients take their prescriptions to a particular pharmacy". It was argued that "inspection of premises by the General Medical Council, along with sanctions for inappropriate behaviour" may help to minimise conflicts of interests and protect patients.

11.63 The Allied Health Professions Federation argued that at an individual registrant level, key documents (such as codes of conduct and ethics and standards of proficiency) "should be inclusive of ethical business practice as an integral part of registrants' scope of professional activity". It also said that all regulators' fitness to practise systems "should address alleged malpractice relating to registrants' business activity". In effect, it is not necessary "to introduce a different type of activity focused specifically on business regulation (nor to invest in separate regulators' consumer complaints service)".

11.64 Skills for Care thought there would be "risks if the Health and Care Professions Council was given powers to regulate social care businesses". It said:

> it is hard to envisage how the regulatory power could be applied as the majority of social workers are not employed in "social work businesses" other than in a small number of cases as sole trader independent social workers, and it is likely to cause confusion amongst employers of social workers.

11.65 The Department of Health noted that there are similar "extant powers" in respect of Dental Corporations which are regulated by the General Dental Council. However, it stated that "the Government has no immediate plans to extend business regulations" and would have concerns about "the potential to cause confusion and overlap with the role of systems regulators".

11.66 The Scottish Government did not support the proposal. It said:

> We have concerns that any alteration to the current powers would create confusion regarding the boundary between professional and systems regulators. In addition, the scope of systems regulators

varies between countries, and bodies such as the Care Quality Commission do not operate in Scotland with the converse being true for Healthcare Improvement Scotland. However, we consider that there may be a place in the new statute for the development of joint working protocols/memoranda of understanding between the regulators and the various systems regulators in England, Wales, Scotland and Northern Ireland.