non-nutritive ingredients. They are sold as supplements and added to foods, but their efficacy is controversial and concern remains over potential harm.³

Functional foods are marketed directly to consumers, who are unable to assess the implied health claims. Consumers thus must rely on their governments to make sure that they are not misled. Unfortunately, current government regulations leave room for misleading claims. Deception is promoted by the fact that legislation of health claims for foods is layered: there are soft claims, which require soft evidence, and hard claims, which require harder evidence. For example, a draft regulation of the Codex Commission of the United Nations, which sets international food standards, recognises claims about nutrient content ("rich in calcium") and disease reduction ("prevents osteoporosis"), as well as various intermediate categories. Manufacturers have therefore made the formulation of soft claims into a fine art, creating claims that imply health effects without actually naming a disease.

Regulations differ between countries. Japan was the first country to recognise functional foods as a separate category when in 1991 it introduced the FOSHU (Foods for Specific Health Use) system to evaluate health claims. This system has valuable aspects: it regulates both safety and health, and it demands that the food be analysed for the amount of effective component.⁴ But it is voluntary, and even though the evidence required has been reduced in recent years and is minimal by pharmaceutical standards, most manufacturers opt for softer categories of claims, which require little evidence. An example is the unproved but lawful statement that extra vitamins help to maintain healthy skin and mucosa. Watering down of regulations has also occurred in the United States, which once had a solid system for disease reduction claims for foods, which were allowed only if there was "significant scientific agreement" that the claim was valid.⁵ However, the Food and Drug Administration's oversight over health claims has eroded, and the United States now allows "qualified health claims" for which there is hardly any evidence, as long as a disclaimer is included. In the European Union the safety of novel foods is thoroughly regulated but health claims are not—EU legislation for nutrition claims is complex, fragmented, and poorly enforced. Paradoxically, current EU regulations prohibit claims that a food ingredient prevents a disease even when the claim is true—for example, that folic acid prevents neural

tube defects. Finally, Canada, Australia, and New Zealand have introduced new systems to regulate health claims, but experience with these is still limited.

The lack of proper regulatory oversight has led to some functional foods that are no more than quackery, while at the same time other functional foods do promote health and prevent disease. The potential for effective functional foods is certainly there. Foods and food components could prevent or ameliorate many diseases,^{6,7} but not enough research is being done to identify effective ingredients and substantiate their efficacy and safety. Whether such research will be done depends to a large extent on proper regulation. Major food companies are eager to expand into health promoting foods, but there is no incentive to underpin such health effects with solid research when products can be successfully marketed on the basis of vague allusions alone. But there is hope. After more than 20 years of deliberations the European Commission recently agreed on new regulations that would prohibit vague claims and that would allow hard claims of disease reduction for foods if the evidence is solid.⁸ The commission even wants to grant companies seven years of exclusivity for truly novel claims backed up by solid data. If the European Parliament accepts these proposals it would be a step in the right direction.

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Suspension of doctors

The process is badly handled at present, and new guidance is welcome

For any employee to be excluded from work is a devastating blow, whatever the circumstances. In the case of doctors the safety of patients may be a justifiable reason, but the process that leads to that decision is not straightforward and in many cases the individuals concerned, their colleagues, and the patients feel confused and uninformed.

A recent report from the National Audit Office has confirmed what many suspected and some have

suffered at first hand—that the process of suspension has to date been haphazard and badly handled in many NHS organisations.¹ Following this report comes new guidance from the Department of Health, contained in a direction to NHS trusts that has to be applied to all suspensions.

The report from the National Audit Office is forthright about the expensive and damaging consequences that result when suspensions are performed badly. The

numbers involved are hard to ascertain, but estimates indicate that at any one time in the past three years more than 30 doctors were suspended for six months or more, and between April 2001 and July 2002, 206 doctors were suspended by NHS trusts in England, with 44% (90) of these suspensions said to be related to issues of professional competence. Costs are estimated at around £29m (\$54.5m; €42m) each year for the NHS as a whole. The human cost cannot be measured so easily, but individuals describe great personal distress, upset to their families, loss of self esteem, helplessness, anger, depression, and a real sense of despair when suddenly removed from a busy working life.²

All this gives good reason for a radical rethink of how these issues are handled on a daily basis. The NHS, the professions, and the Department of Health have recognised for a long time that doctors' disciplinary issues are difficult and complex, and perhaps made more so by the fragmented legalistic frameworks that have governed them for many years. In an important step the NHS Confederation, the BMA, and the British Dental Association have agreed new guidance with the Department of Health on the initial handling of concerns about doctors and dentists in the NHS.³ This comprises the first two parts of a planned five part framework and covers "action when a concern arises" and "restriction of practice and exclusion of practitioners at work." NHS trusts have until April 2004 to put the new arrangements in place in their organisation and to report their actions to strategic health authorities.⁴ The next three parts will, after further discussions, cover conduct hearings, dismissal, and the handling of capability and health issues.

The approach has four key elements: building on appraisal and revalidation as a way of recognising early potential difficulties and dealing with them; using the advisory and assessment services of the National Clinical Assessment Authority to improve management of cases; tackling the "blame culture"—recognition that most failures in standards of care are caused by weaknesses in systems rather than individuals; and abandoning the suspension culture with new regulations, which will prohibit gardening leave and will provide for the possibility of immediate exclusion (usually only on the grounds of patients' safety) for a maximum of two weeks. Any further exclusion must be formalised with the National Clinical Assessment Authority and a senior case manager appointed within the trust (usually the medical director); a non-executive board member will be made responsible for overseeing progress. In most instances a carefully managed internal investigation will lead to the development of an action plan that can be agreed by all concerned. In a few cases a full assessment by the National Clinical Assessment Authority may be needed.

The guidance reflects a determination to stamp out the knee jerk reactions and loose management of cases that the National Audit Office report has highlighted. The emphasis is on quick and appropriate investigation of allegations, adherence to reasonable time scales, and full consideration of alternatives to exclusion. In response to concerns that some doctors were not clear about the case against them or given any opportunity to respond to allegations in a denial of natural justice, the guidance stipulates that the practitioner should be told the nature of the allegations

before a formal exclusion is made and given the opportunity to state his or her case and propose alternatives to exclusion. This reflects an appreciation that some doctors were unaware that their behaviour was causing concern until they found themselves suddenly suspended, with no opportunity to explain or make amends. By compelling senior managers in trusts to think so carefully around the reasons for exclusion, the guidance implicitly recognises the damage that can be done when an individual is prevented from working.

Suspension may be a neutral act in employment law, but the subject and others rarely perceive it that way. Neither will it be considered a neutral act if it continues for too long without proper investigation while the doctor's skills and confidence are allowed to decline. Matters that are already difficult to disentangle (and no one can pretend that these issues are easy) have often been made worse by poor leadership in trusts, resulting in reactive and apparently arbitrary decisions being made, followed by hurried implementation in a very uncaring and unsupportive way. The use of informal gardening leave has led to much more confusion and bad practice, even when intended as a less severe process.

The report from the National Audit Office and the guidance and directions from the Department of Health represent progress and are to be welcomed. However, trusts need to recognise that the key people who have to deal with these critical issues—the medical director and the director of human resources—often lack the knowledge, competencies, and experience to be effective. Training in understanding the process, access to good legal advice, and acting with objectivity and integrity and with empathy for those involved must form an important part of the way forward if there are to be improvements in practice.

We as doctors must become our own experts and also recognise that at least one of the reasons that things have been bad is the lack of willingness of doctors themselves to accept that sometimes things go wrong, and that open and fair processes need to be agreed and in place in advance to deal with them in a non-confrontational way. The report from the National Audit Office and the guidance should be discussed at every medical staff committee in the next few months, for it is in everyone's interest for doctors to work with their trust managers to agree local implementation in a way that will be supportive and effective. Enthusiastic involvement in regular appraisal and mentoring will be other ways in which the profession can minimise problems that, if they are brought to light only by a suspension, will have already gone too far.

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