for the Regulation of Forensic Practitioners includes repeated review of a random selection of recent reports, as well as measures of professional good standing.

The Civil Justice Council's actions have coincided with the adoption by commercial organisations, medical associations, and societies for experts of the Civil and Draft Criminal Procedure Rules as the basis for audit tools and protocols to help their employees and members achieve high and consistent standards.

In allowing Meadow's appeal the Court of Appeal did more for expert witnesses than simply overturn the GMC's decision to strike Meadow off the register. It also ruled that witnesses in court cases who gave evidence in good faith should be protected against disciplinary action by regulatory bodies, thus extending the protection witnesses already have from civil actions. The only exception would be if the judge in the case referred an expert to a regulatory body.

The GMC is concerned that this judgment places medical experts beyond the reach of discipline, unless the judge reports them to their regulatory body.[11] This fear may not be well grounded. The appeal court judge's reasoning was that experts should be able to "give their evidence fearlessly" and that in the absence of immunity, which he conceded could be narrowly defined, "the administration of justice would be greatly impeded if witnesses were to be in fear that any disgruntled or impecunious person against whom they give evidence might subsequently involve them in costly litigation."[12]

The judge made it clear that there were precedents for this approach, and that the limited immunity applied only to reports made in good faith and following the principles laid down in the *Ikarian Reefer* case (an insurance dispute about a grounded ship where the judge set out much-quoted principles about the independence and duties of expert witnesses) and subsequently codified.[9] Where experts have deviated from good practice they have been censured[13] and have even been forced to pay costs.[14] The appeal court judge also said that where a report to the regulatory body by the judge was warranted the expert should have an opportunity to make representations before the referral was made. About Meadow's specific case he did not say there should be no sanction, rather that the sanction imposed by the GMC was excessive: "The imposition of a condition not to engage in medico-legal work would have been appropriate."

Thus the appeal court has gone some way to reduce the deterrents to experts' practice. The judge was careful to point out that honest but seriously deficient evidence, whether from ill health or otherwise, would continue to risk referral and sanction. A pendulum that had swung too far one way has now returned much closer to equilibrium.

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Harmful impact of EU clinical trials directive

Academic clinical research in cancer seems to have no future in Europe

Innovative clinical and translational research, instigated and conducted by motivated physician-scientists, has had an important part in the development of modern oncology. For example, adjuvant treatments for breast and colorectal cancer, shown in randomised trials to be effective in preventing recurrence, have been developed and tested through research performed largely by academic clinicians.[1–3] Similarly, such clinicians have been responsible for researching, developing, and introducing sentinel node biopsy and breast conserving surgery, which have reduced morbidity for many hundreds of thousands of women.[4 5] Yet investigator initiated academic clinical research is under threat—ironically, from a European Union directive that is aimed at protecting patients and improving research standards.

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The official goals of the EU clinical trials directive, implemented in 2004,[6] were to improve the protection of patients and the reliability of research reporting and to harmonise and increase the competitiveness of European clinical research. The responsibilities of the research sponsor were increased significantly, and at the outset many investigators were worried that that the labour intensive, bureaucratic, and expensive endeavour of running a clinical trial would become worse.[7] In particular, academic researchers funded by grants, who have so far performed most oncology trials, were worried that their resources might no longer suffice to meet the requirements of the new directive. A recent analysis of research since the directive suggests that many of those fears have been realised.

The European Organization for Research and Treatment of Cancer (EORTC), the largest independent cancer research network in Europe, recently analysed the effect of the directive its trials (P Therasse, European Cancer Conference, Paris, Nov 2005). The number of new trials fell from 19 in 2004 to seven in 2005 (63%), and a third fewer patients were enrolled. Simultaneously, trial costs increased by 85% and insurance costs from 70m to 140m euros. Trial initiation was about five months slower than in 2004, mostly the result of the increased workload of ethics committees. Paperwork and documentation increased "a lot."

Instead of benefiting patients, the EORTC thought that the directive had hindered their access to new treatments. Moreover, the organisation reported significant variations in the way the directive was interpreted in different countries, suggesting unsuccessful harmonisation. On the positive side, the employment of EU officials and contract research organisations (to do the work that clinicians don't have the time to do) was thought to be improved.

Our own experiences are in accordance with EORTC findings. For example, we are taking part in multinational randomised studies of an antiangiogenesis agent, given in combination with standard therapy. Many participating patients have advanced disease and are very ill. Yet the directive requires reporting of all suspected serious adverse events, regardless of whether they are caused by the underlying disease, chemotherapy, or by the investigational drug. Information on each such adverse event needs to be distributed globally to all investigators working on the molecule. The Finnish coordinating investigator has already received 219 faxes, each consisting of 2-36 pages. The directive also requires that each event is reported to local ethics committees, together with an ethical evaluation; so far these have been discussed in 14 sessions of the Tampere ethics committee.

In the ethics committee that reviews surgery and oncology trials in Helsinki, the number of approved applications has steadily decreased from 120 in 2002 to 70 in 2005 (42% decrease). These numbers include both academic and company sponsored trials and also permits for the use of clinical specimens (A Keskinen, personal communication). Academic drug trials decreased from 20 to five between 2003 and 2005 (75% decrease). Nevertheless, the workload of the committee increased, because protocol amendments increased from 18 to 69 (283%) and reports of serious suspected adverse events from 16 to 138 (763%).

These numbers seem to confirm the initial worries about the future of investigator initiated clinical cancer research. Current and future patients with metastatic cancer should be worried. If clinical and translational research is thwarted the newest or most effective therapies may not become available rapidly. The rational development of cancer treatments may be at risk if enrolling patients into trials requires insurmountable efforts from the practising physician. In the era of evidence based medicine, it is noteworthy that these increased requirements are not based on evidence of benefit to patients.

If the current situation is increasingly difficult for industry supported research, academic translational research aimed at testing novel therapies is in particularly dire straits. Academic translational research has yielded many of the great medical discoveries (such as antibiotics and vaccines) but is now practically impossible without drug company support. The directive requires that even phase I trials fulfil pharmaceutical industry grade good manufacturing practice standards, comprehensive preclinical biodistribution and toxicity experiments, and qualified person status for importing experimental drugs between countries. Taken together, these requirements make conducting trials too expensive for investigators supported exclusively by grants.

The development of unconventional approaches such as cancer vaccines and cell and gene therapy has suffered the most, because such approaches have not been attractive to pharmaceutical companies owing to complexities in intellectual property and manufacturing. Moreover, in many European countries drug development is considered an activity conducted only by pharmaceutical companies, which has resulted in inadequate financial support to academic groups. Consequently clinical researchers have had little impact in the decision making process on new treatment strategies. The directives and rules for European clinical research are designed by the Enterprise and Industry Directorate General and not by branches responsible for health care or research (http://europa.eu.int/comm/dgs_en.htm). This may explain why rapid development of new strategies for severely ill patients seems to have received little priority.

New directives on clinical research are in preparation (http://pharmacos.eudra.org/F2/). Therefore, now is the time for action by physicians, patients, universities, and politicians to ensure that academic, investigator initiated translational research can continue in Europe. It is in no one's interest if only commercial corporations have the resources to plan and carry out clinical trials.

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