

for the journal? Scientific publishers cannot be expected to absorb the costs of running articles through peer review and printing them if they will lose most of their sales because readers get their copies direct from the authors (who will note proudly on their manuscripts that the articles have been peer reviewed and accepted by X Journal).

This issue arises in theory even if the journals do get an assignment of the copyright, if authors as a group are successful at negotiating licences to distribute their work. Even without a licence, the author may be free after transfer of the copyright to make at least some kinds of distribution as a 'fair use'.

In the United States, whether the scholar or the university owns the copyright has not been firmly decided. A straightforward reading of the Copyright Act leads to the conclusion that the university owns the copyright (subject to negotiation with the members of the faculty) as a work made for hire. But at least two important judicial decisions have found a 'professor's exception' to the work-for-hire doctrine, based on long tradition at universities.

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Who pays what in drug development

Sir — Henry Miller¹ repeats the much quoted claim that "bringing a drug to market in the United States now costs more than \$500 million," adding that this is "by far the highest price tag in the world".

Miller's letter gives the misleading impression that drug companies spend hundreds of millions of dollars on the tests needed for US Food and Drug Administration marketing approval. The costs of drug development are not trivial, but the figures Miller cites are based mostly on estimates of the costs of preclinical research, rather than FDA regulatory burdens. The most detailed study of the costs of clinical trials was a 1991 *Journal of Health Economics* paper². In 1997 prices, the average out-of-pocket costs of clinical trials needed for FDA approval were \$25 million. Adjusted for risk, the 'per approval' cost of clinical trials was \$56 million.

The \$500 million figure quoted by Miller and others adjusts these costs somewhat higher to include 'capital costs' for financing trials, but also and most importantly the cost of preclinical research, which accounts for 70 to 80 per cent of the total cost of drug development in some studies.

Moreover, it is often governments rather than the drug companies that pay for

clinical and preclinical research. For example, according to US tax returns, from 1983 to 1993 the pharmaceutical industry reported expenditure of only \$213 million on clinical trials for orphan drug development. This was about \$2.3 million for each of the FDA's 93 orphan drug approvals during the period.

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1. Miller, H. *Nature* **395**, 835 (1998).
2. DiMasi, J. A., Hansen, R. W., Grabowski, H. G. & Lasagna, L. *J. Health Econ.* **10**, 107–142 (1991).

Guard your knowledge... and reap the rewards

Sir — The British government's desire to put "the commercialization of scientific knowledge at the heart of its industrial policy" is timely (*Nature* **396**, 714–715; 1998). The ideal is a seamless integration between public and privately funded research with scientists having interests in both sectors.

However, what constitutes knowledge generated from academic, publicly funded research? Knowledge is any privileged information which can generate or add value to intellectual property and, when exploited, can be sold for profit. A conversation over coffee or a discussion at a poster cannot be valued but nevertheless is the transfer of knowledge. So is the perusal of grant applications and papers submitted for publication. At present the exploitation of this knowledge is unregulated.

Without safeguards and procedures to ensure that knowledge, however defined, is properly valued, funding agencies will lose rewards to which they should be entitled.

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German university reforms misguided

Sir — Your editorial "When payment by results is a sensible approach" was ill-informed and superficial (*Nature* **396**, 393; 1998). You highlighted suggestions from Germany's University Rectors' Conference (HRK) that new performance-dependent criteria should be applied to universities to increase efficiency and cut costs: that the pay of senior academics should be performance dependent, and that lifetime tenure should be abolished.

These suggestions would exacerbate the

problems. First, it is true that German professors receive a sum of money for running costs which is not dependent on their research performance. However, often this sum barely covers the costs of teaching and departmental maintenance which are aggravated by service costs for large equipment as required by law. Running a modern research programme on this money is generally out of the question.

Second, a performance-dependent scale that is partially indexed by the amount of external funding is a questionable criterion. Within Germany there is a large pool of industrial money which is extensively used by academics. However, many of these collaborative grants are scientifically mundane and unchallenging. The criteria for success in winning such a grant are fundamentally different to those for public-sector grants. At present the only funding source that guarantees scientific excellence is the Deutsche Forschungsgemeinschaft, which is coming increasingly under financial pressure. So, judging performance solely by the amount of external funding would drag German science in the direction of mediocrity.

Another major difficulty is the assignment of performance indexing to a body within the university. Major decisions in German universities are often highly political and subjective. At present, this situation is usually tolerable as the personal status of the individual is not open to influence. The HRK suggestions seek to change this. I dread to think of the incestuous consequences this would bring.

The suggestion that tenure should be abolished to improve efficiency is at best surprising. All other European countries award tenure to academics on the assumption that, despite possible negative consequences, it is essential to ensure long-term planning for scientific programmes.

Many see the HRK developments as a political manoeuvre on the part of the technical high schools (*Fachhochschulen*), which are essentially teaching establishments, to attain full university status without having to fulfil the present requirements for research excellence. This has been a point of contention for years, as salaries in the *Fachhochschulen* are slightly lower than in the universities but would become equal under the HRK recommendations because the university professorial salary would be lowered.

The real problems facing university academics are that research groups are often too large and run on an imperialistic basis, and that funding opportunities for young scientists to organize independent research groups are too limited.

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