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Are increased, but the risk is difficult to separate from the higher risk associated with the condition itself, say Parker Magin and John Sullivan
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EU legislation offers an exclusive marketing period as an incentive for companies to develop drugs for rare diseases. But pricing for orphan drugs hinders access and may warrant a competition law investigation, say Jonathan C P Roos, Hanna I Hyry, and Timothy M Cox

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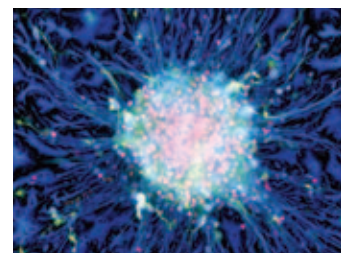
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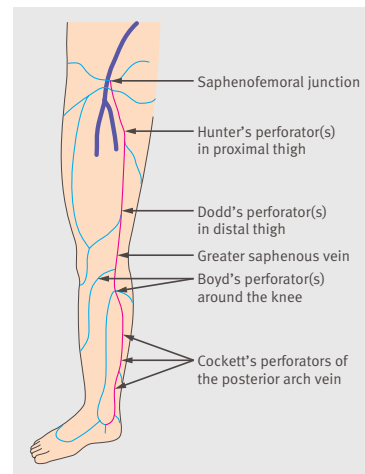
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20 November 2010 Vol 341

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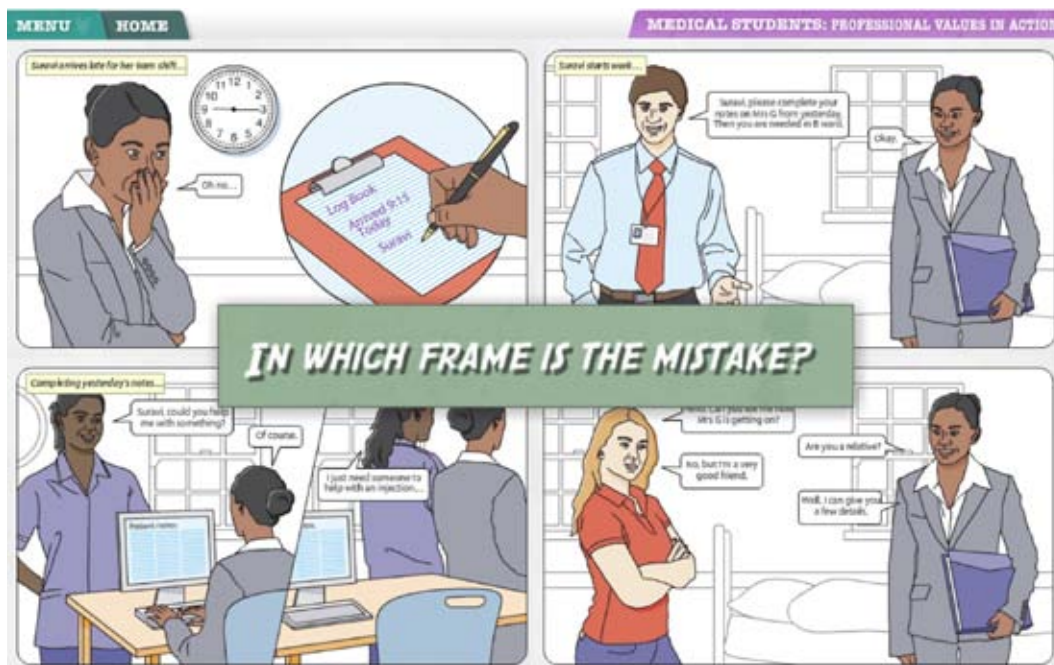
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Published weekly. US periodicals class postage paid at Rahway, NJ. Postmaster: send address changes to BMJ, c/o Mercury Airfreight International Ltd Inc, 365 Blair Road, Avenel, NJ 07001, USA. \$796. Weekly
Printed by Precision Colour Printing Limited

PICTURE OF THE WEEK

The General Medical Council has created an interactive website for medical students to bring its guidance to life and help understand how it would be applied in day to day situations. Students can spot the mistake in the cartoons and test their knowledge through quizzes and case studies. Visit www.gmc-uk.org/studentvalues

THE WEEK IN NUMBERS

1999 Year the *BMJ* adopted open peer review (Head to Head, p 1082)

172 950 Number of people who opened HealthSpace accounts (personal electronic health records) between 2007 and October 2010; this is 0.13% of those invited, considerably less than the 5-10% expected.
(Research, p 1091)

1% Proportion of western Europe's total annual healthcare budget that is spent on treating venous leg ulcers (Clinical Review, p 1092)

48 hours The time frame in which transplantable tissues must be removed from the donor (Practice, p 1097)

QUOTES OF THE WEEK

“Legislation on orphan drugs, far from encouraging the development of new treatments for orphan diseases, is severely limiting the availability of existing treatments”

Neurologists and paediatricians call for action on “massive” rises in the prices of orphan drugs in an open letter to the prime minister, David Cameron, and the health secretary, Andrew Lansley (Observations, p 1079)

“One method, used in Guantanamo Bay, involved putting prisoners in a box with an insect—after first reassuring them that the insect had neither a venomous sting nor bite”

Liam Farrell, general practitioner, Crossmaglen, County Armagh, on torture (The Best Medicine, p 1108)

EDITOR'S CHOICE

Stop exploiting orphan drugs

With minor adjustments to the product and new packaging, a modestly priced drug suddenly becomes unaffordable

The most surprising revelation in this week's *BMJ* is that there's a website that lists drugs that can be "orphaned" and exploited for profit. In an open letter to Britain's prime minister, 21 neurologists and paediatricians call for an urgent review into the pricing of orphan drugs (p 1079). Legislation meant to encourage development of new treatments for rare diseases is instead severely limiting availability of existing treatments, they say, costing the taxpayer unnecessary millions and reaping massive profits for drug companies.

As Nigel Hawkes and Deborah Cohen describe (p 1076), a company needs only to find an unlicensed drug and license it for use in a rare condition, citing little more than pre-existing evidence of its use in clinical practice. With minor adjustments to the product and new packaging, a modestly priced drug suddenly becomes unaffordable. A 10 year monopoly (seven years in the United States) then protects the drug from competition, banning previous suppliers from producing and distributing the unlicensed version and clinicians from prescribing it.

This is so clearly against the interests of patients and the public that the inaction of governments and drug regulators is astounding. Some countries have acted, say Robin Ferner and Dyfrig Hughes in their editorial (p 1059). In France a government agency makes and distributes unlicensed drugs for rare diseases, overcoming claims that a drug's quality can't be assured without industry intervention. Our editorialists ask why the NHS doesn't do this. And they call on the General Medical Council to lift the ban on prescribing an unlicensed drug where a licensed drug exists for the same indication.

Jonathan Roos and colleagues say the situation warrants investigation under competition law

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Career Focus, jobs, and courses appear after p 1108

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(p 1084), while the authors of the open letter invoke the parliamentary health select committee and the Office of Fair Trading. It's clear that something must be done—and, given the financial state of health systems around the world, the sooner the better.

Less clear are the merits of open peer review in which authors know the identity of their reviewers. Karim Khan says it won't work for most journals (p 1082). But Trish Groves explains that editors of the *BMJ* have long been convinced of its ethical superiority (p 1082). A randomised trial in 1999 gave us enough evidence to introduce such a system, and 10 years' experience has confirmed our view that it works.

We were keen to take things further, to post reviewers' signed comments online with the published article, giving reviewers more credit and accountability for the good work they do and helping readers understand how decisions are made. So we did another randomised trial. The reassuring results were just coming in when I moved to help set up BioMed Central in 2000. So all articles published in BMC's new open access medical journals were accompanied by their pre-publication history, including signed reviewers' comments and the submitted version of the article. This system has been running successfully for 10 years.

But the *BMJ*'s randomised trial had a sad history. Its first author, Sue van Rooyen, fell seriously ill. She died in 2005. This week we finally publish the trial (p 1088), and we will start posting reviewers' comments with all published research papers next spring. In the meantime we look forward to hearing from volunteers who would like their research peer reviewed under the new system.

Fiona Godlee, editor, BMJfgodlee@bmj.com

Cite this as: *BMJ* 2010;341:c6587

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