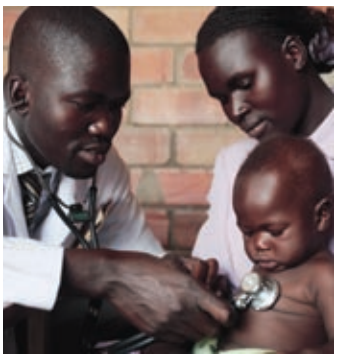

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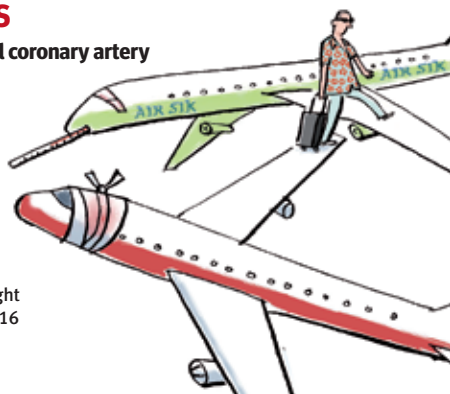

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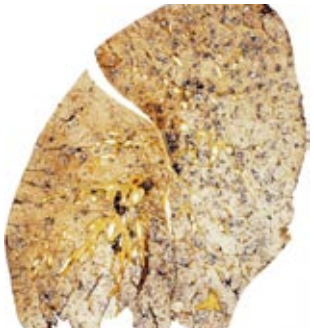
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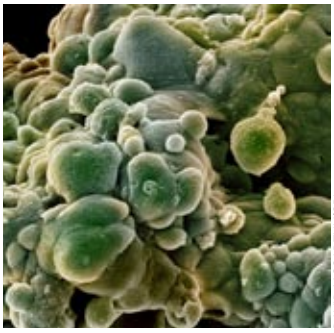
DAVID MCCARTHY/SPL

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RESEARCH

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PRACTICE

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HOLD THE BACK PAGE!

As you may have noticed, we recently combined the *BMJ* and *BMJ Careers* within one set of covers. This has presented some practical problems, one being the splitting up of the obituary pages. We intend to move the obituaries further forward so the short and long obituaries are together again and, by doing this, we will gain a page for editorial content at the back of Minerva.

We have now finalised the format for this page, which we have called Endgames. There will be a regular statistics question, case report, clinical and picture quiz, along with a question of the week from OnExamination to test your knowledge. If you would like to submit questions for this page please refer to our advice for authors on bmj.com (http://resources.bmj.com/bmj/authors/types-of-article) or contact Amy Davis (adavis@bmj.com).

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The Editor, BMJ
BMA House, Tavistock Square, London WC1H 9JR
Email: editor@bmj.com
Tel: +44 (0)20 7387 4499
Fax: +44 (0)20 7383 6418
BMA MEMBERS' INQUIRIES
Email: membership@bma.org.uk
Tel: +44 (0)20 7383 6642
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PICTURE OF THE WEEK

Motivational deficiency disorder, the spoof illness which started life on the internet two years ago as a satirical dig at drug industry marketing strategies, is now the subject of a fake television "story" designed as an educational aid for the public and health professionals. The new video clips, available online, are part of Consumers International Marketing Overdose campaign, and show a stricken woman unable to get off the sofa without the aid of miracle drug Strivor. See Observations p 589.

THE WEEK IN NUMBERS

57 Number of countries with a shortage of healthcare workers, of which 36 are in Africa **(News p 579)**

14 Number needed to treat for one person to quit smoking at one year after telling patients their lung age **(Research p 598)**

20% Proportion of people over 70 who take five or more drugs **(Clinical Review p 606)**

9000 Number of men who die from prostate cancer in England and Wales each year **(Guidelines p 610)**

40% Estimated proportion of counterfeit drugs in Lagos, Nigeria, at the end of the 20th century **(Review of the Week p 617)**

THE WEEK IN QUOTES

"At a conference last year, the UK Medical Protection Society said it had no record of anyone being sued for helping during an in-flight medical emergency" (Features p 584)

"In an age of evidence based medicine, the marketing of genetic tests with little evaluation is an unwelcome anomaly" (Analysis p 590)

"Systematic reviewers should routinely assess the risk of bias in the results of trials" (Research p 601)

"Will the traditional, small, local family practice be subsumed into McDonald's-style medical franchises?" (From the Frontline p 618)

EDITOR'S CHOICE

A legal framework for drug safety

Cover illustration: Malcolm Willett
Feature, p 584
Personal View, p 616

It's welcome news that the UK government will close the legal loophole that allowed GlaxoSmithKline to escape prosecution last week for not disclosing evidence of increased suicide risk in children taking seroxat (News p 576). But this piece of legislation alone is not enough. It should be seen as just one further step on the legislative road to full mandatory disclosure of data from clinical trials.

There's no mistaking the UK regulator's frustration at having to drop its attempts to prosecute GSK. Staff at the Medicines and Healthcare products Regulatory Agency reviewed thousands of documents dragged out of GSK over four years. But in the end the existing EU legislation let them down: at the time it didn't require companies to disclose adverse events from trials in groups of patients for whom the medicine was not licensed. On the basis of the same data but in a different legal framework, New York state successfully prosecuted GSK in 2004 for persistent fraud (*BMJ* 2004;329:590).

In his letter to GSK, Kent Woods, the MHRA's chief executive, said it should be self evident that information on adverse effects should be made available promptly in order to protect the public's health: "That moral responsibility now needs to be insisted upon by the unambiguous force of the law." (http://tinyurl.com/38sggg)

This raises the question of whether there is a stronger moral responsibility on the drug industry to ensure safety than on, say, the catering or transport industries. Whether there is or not, this case has shown that moral responsibility alone cannot be relied on. Commenting on last week's other drug industry story—the successful efforts by the makers of Gaviscon to delay the development of a generic alternative (News p 576)—Joe Collier says that whatever efforts are made to tighten the law or industry codes of conduct, companies will find a way to push their boundaries to the limit: "Doctors, government, and regulators of medicines have got to recognise that the industry may not have the best interests of patients or the NHS at heart."

The new UK legislation will remove any remaining doubt about a company's responsibility to declare all evidence on adverse effects, whether before or after marketing, on or off label, within or outside the EU. In addition, the health secretary should undertake a thorough review of the current legal framework for ensuring the safety of prescribed drugs. Legislation similar to the new FDA Amendment Act in the United States, which mandates timely disclosure of trial results for all drugs and devices (*BMJ* 2008;336:170), should be enacted across Europe, with additional measures to ensure that the disclosed data are comprehensive and meaningful and include the trial protocol.

The drug industry has made progress towards greater transparency, both voluntarily and under pressure from journals and regulators. But there are limits to the force of moral responsibility. So for everyone's sake let's rely on the law and make sure it is strong, clear, enforceable, and enforced.

Fiona Godlee, editor, *BMJ* fgodlee@bmj.com

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***Drug and Therapeutics Bulletin* March issue**
Reviews on when the child has a fever and risks of extended-spectrum beta-lactamases and an elaboration on diabetes and driving
dtb.bmj.com

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PLUS
Career Focus, jobs, and courses appear after p 620.

Articles appearing in this print journal are likely to have been shortened.
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