



# How to change your life in a week

G2 special



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Newspaper of the year

## Scientists find way to slash cost of drugs

### Indian-backed approach could aid poor nations and cut NHS bills

Sarah Boseley  
Health editor

Two UK-based academics have devised a way to invent new medicines and get them to market at a fraction of the cost charged by big drug companies, enabling millions in poor countries to be cured of infectious diseases and potentially slashing the NHS drugs bill.

Sunil Shaunak, professor of infectious diseases at Imperial College, based at Hammersmith hospital, calls their revolutionary new model "ethical pharmaceuticals".

Improvements they devise to the molecular structure of an existing, expensive drug turn it technically into a new medicine which is no longer under a 20-year patent to a multinational drug company and can be made and sold cheaply.

The process has the potential to undermine the monopoly of the big drug companies and bring cheaper drugs not only to poor countries but back to the UK.

Professor Shaunak and his colleague from the London School of Pharmacy, Steve Brocchini, have linked up with an Indian biotech company which will manufacture the first drug – for hepatitis C – if clinical trials in India, sponsored by the Indian government, are successful. Hepatitis C affects 170 million people worldwide and at least 200,000 in the UK.

Multinational drug companies put the cost of the research and development of a new drug at \$800m (£408m). Professors Shaunak and Brocchini say the cost of theirs will be only a few million pounds.

Imperial College will hold the patent on the hepatitis C drug to prevent anybody attempting to block its development. The college employs top patent lawyers who also work for some of the big pharmaceutical companies.

Once the drugs have passed through clinical trials and have been licensed in India, the same data could be used to obtain a European licence so that they could be sold to the NHS as well.

Professor Shaunak says it is time that the monopoly on drug invention and production by multinational corporations – which charge high prices because they need to make big profits for their shareholders – was broken.

"The pharmaceutical industry has convinced us that we have to spend billions of pounds to invent each drug," he said. "We have spent a few millions. Yes, it will be a threat to the monopoly that there is."

"I'm not only an inventor of medicines – I'm an end user. We have become so completely dependent on the big pharmaceutical industry to provide all the medicines we use."

"Why should we be completely dependent on them when we do all the creative stuff in the universities? Maybe the time has come to say why can't somebody else do it? What we have been struck by is that once we have started to do it, it is not so difficult."

The team's work on the hepatitis C drug has impeccable establishment credentials, supported by a grant from the Wellcome Trust and help and advice from the Department for Trade and Industry and the Foreign and Commonwealth Office.

But the professors' ethical pharmaceutical model is unlikely to find much favour with the multinational pharmaceutical companies, which already employ large teams of lawyers to defend the patents which they describe as the lifeblood of the industry.

One industry insider envisaged legal challenges if the new drugs were not genuinely innovative. It could become "a huge intellectual property issue", he said.



Ellie Lawrenson, who was killed by her uncle's dog early yesterday morning

## Owner was warned over dog that killed girl, 5

David Ward

The owner of a "pit bull-type dog" which killed a five-year-old girl in the early hours of New Year's Day was warned to keep his pet under control seven months ago, it emerged last night.

Ellie Lawrenson died in the living room of her grandmother's house on a quiet estate on the edge of St Helens, Merseyside, after choosing to remain there rather than return home with her parents, who had been out celebrating.

A spokeswoman for St Helens council said that a council dog warden had written to the dog's owner, named locally as Ellie's uncle, Keele Simpson, last May after a complaint by a neighbour over an attack on another dog.

Last night a 69-year-old man claimed he was attacked by the dog, Reuben, in September last year, but managed to hold it at bay with his walking stick. The neighbour, who did not want to be named, told the Press Association he had reported the attack to the police and dog wardens, who later visited the owner's home.

Police were last night trying to establish why the dog attacked Ellie; it is unclear whether she was asleep at the time. Police said she died of severe neck and head injuries. Her grandmother, Jackie Simpson, 46, tried to pull the dog off Ellie, and suffered serious injuries to her arms and legs. She managed to drag the dog from the house into a fenced-off area where it was shot by a police officer.

Last night a police spokeswoman said police and council officials were trying to establish whether the animal had a violent history. She said: "We think we were aware of the report of the dog attacking another dog in May, but we're not aware of any report from September. And we've come across no mention of the animal attacking a person."

It is understood that officers called to the scene were later sent home after witnessing the child's injuries. Detectives are investigating whether any offences have been committed under the Dangerous Dogs Act.



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### National

#### Civil servants ballot on strike action

More than a quarter of a million civil servants are being balloted today for disruptive action across Whitehall over pay, compulsory redundancies and privatisation of services. The action would target the collection of billions of pounds of tax remissions due by the end of this month. Millions of taxpayers are to be urged to send tax returns and remissions early in an attempt to mitigate the impact of the action. The ballot is expected to lead to a "yes" vote, resulting in the first national strike in Whitehall for nearly 20 years and confrontation with the government not seen since Margaret Thatcher was prime minister. 12 >>

### National

#### Boxer Prince Naseem Hamed has been stripped of his MBE after his 15-month jail sentence for dangerous driving



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### International

#### Britons told to keep out of Thai capital

The thousands of Britons who travel to and through Bangkok every week were warned yesterday to defer travel until further notice after the worst bombings in the Thai capital in decades. The government, installed by the military last year, blamed politicians who had lost out in the coup for attacks which killed three and injured 38, including two Britons; one police chief said it had been Bangkok's worst incident in his 40-year career. The Foreign Office warned Britons to avoid Thailand, saying there was a high threat from terrorism throughout a state once regarded as among south-east Asia's most stable and safe. 14 >>

### Financial

#### Go west, cry young househunters

The south-west of England has gained a net 303,000 people in a decade, the highest internal migration in the UK. London has suffered the biggest fall – a net 774,000 Londoners, one in 10, leaving since 1996 for elsewhere. Devon and Cornwall attract retirees but also young business people attracted by its "cool" image, according to research by the Halifax bank; the region's property prices rose 202% in the 10-year spell. City bonuses, migration from east Europe, and recycled wealth from the Middle East boosted house prices in the capital, while nationally prices will rise 5%-8% this year, again led by London and the south-east. 22 >>

### Sport

#### Barneveld wins world darts thriller

Raymond van Barneveld came back from three sets down against Phil "The Power" Taylor to win PDC World Championship in Purfleet last night in one of darts' greatest ever finals. Van Barneveld took the title with a double 20, having missed five earlier chances to close out the match, in sudden death leg to win 7-6. With a huge smile across his face and the £100,000 winner's cheque in his pocket, Van Barneveld was full of praise for his opponent. "If Phil ever retires, they should build a statue of him. He is the greatest ever player, but this night is the greatest of my career," he said. Sport, 13 >>

## News

# Scientists on a mission to bring cheap drugs to the world's poorest countries

## Indian trials for low cost hepatitis C treatment

### Researchers pioneer 'ethical pharmaceuticals'

Sarah Boseley  
Health editor

Until recently, hepatitis C, a potentially fatal blood-borne infection that could affect as many as 500,000 people in the UK, was treated with the antiviral drug ribavirin, together with interferon.

The drugs are old enough to be out of patent and so can be made cheaply, but the necessary frequent injections of interferon cause serious side effects.

Then in 2003 scientists working for Roche and Schering Plough developed a variation on the drug designed to last longer in the blood and so require fewer injections. The trial results were spectacular – half of the patients were cured. The drug was patented and is sold to the NHS.

The catch, as so often when it comes to cutting edge pharmaceuticals, is cost: the £7,000-a-course price tag is expensive for the NHS and beyond the budgets of developing countries, where the need is greatest.

Enter Sunil Shaunak, professor of infectious diseases at Imperial College, and his colleague from the London School of Pharmacy, Steve Brocchini. Involved in the battle to contain the Aids pandemic from its outset in 1985, Professor Shaunak was committed to finding ways to provide cheap medicines for people in the developing world.

In the case of hepatitis C, Professors Shaunak and Brocchini decided to try to make a different, improved version of the Roche drug which would be cheap and stable in a hot climate. They redesigned the drug, known as pegylated interferon, so that it would have the large sugar molecule which made it last longer in the blood on the inside, rather than the outside. Then they contacted a company called Shantha in Hyderabad, which had made the world's first cost-effective hepatitis B vaccine and was already making the original interferon. Shantha has agreed to make the new medicine and the Indian government will subsidise the clinical trials which have to take place before licensing.

"If it works in India, it will eventually come back to the NHS," said Professor

**2-3%** Cost of treatment developed by Prof Shaunak to treat fatal sandfly-borne disease compared to conventional drug

Shaunak. "What we started doing is creating this model of what we call ethical pharmaceuticals."

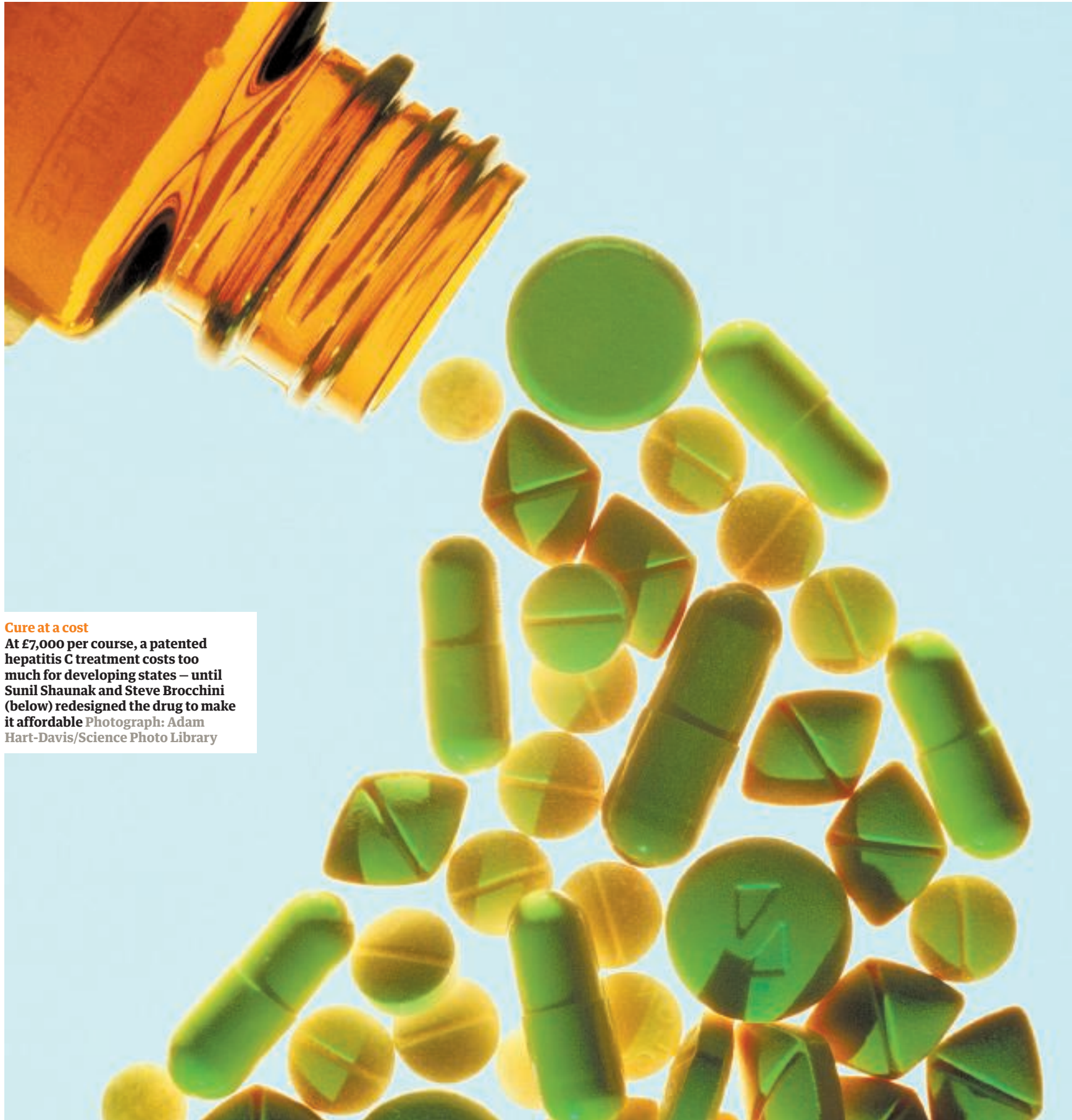
Professor Shaunak says they want to make a difference – not just create new drugs but see them through to become good medicines to treat people in poor countries. He says the model is not a threat to the pharmaceutical giants, but "if eventually it became a threat to their business, I [would] be very flattered". He wants the idea of the model in the public domain so that other young academic doctors and scientists can use it.

The pair are now working on a drug for visceral leishmaniasis, also known as kala-azar – a fatal disease transmitted by the sandfly. Most cases are in Brazil, Bangladesh, India and the Sudan. The 70-year-old drug commonly used to treat it kills 10% of patients. A new drug, Gilead's patented Ambisome, revives patients within hours of the first injection and has few side effects, but costs \$800 (£408).

Gilead's medicine is derived from a very toxic drug called amphotericin B, which, essentially, its scientists inserted into a fat globule, eliminating the toxicity.

Professors Shaunak and Brocchini came up with the idea of putting it into sugar-based polymers instead to make a drug that is stable in hot climates and will cost 2-3% of the price. They have teamed up with the Drugs for Neglected Diseases Initiative (DNDi), a not-for-profit organisation which was the brainchild of Médecins sans Frontières, which will raise the initial money.

Simon Croft of DNDi said the idea was



**Cure at a cost**  
At £7,000 per course, a patented hepatitis C treatment costs too much for developing states – until Sunil Shaunak and Steve Brocchini (below) redesigned the drug to make it affordable Photograph: Adam Hart-Davis/Science Photo Library

## FAQ Affordable medicines

### What are ethical pharmaceuticals?

They are drugs modelled on successful but expensive medicines, that have been structurally modified. It is hoped that the changes will make the new drug more suitable to the hot climates of developing countries but also technically turn it into a novel medicine which is no longer under patent to a big pharmaceutical company.

### Can the new drug be manufactured and marketed straight away?

No – as a new drug, it must be put through clinical trials on patients, which will last several years. Then the data must be submitted to a drug regulatory body for a licence.

### Won't that cost a lot of money?

The trials of the first drug, for hepatitis C, will be cheaper because they are in India and the government will pay – hepatitis C takes a big toll of economically productive people. Manufacturing will also be cheaper there. Grants from philanthropic bodies like the Wellcome Trust pay for the initial development work in the UK.

### How are these drugs different from the cheap generic medicines used against HIV in Africa?

Generics are exact copies of existing medicines. Indian patent law al-

lowed generic manufacture until last year (2006) and world trade rules permitted their sale to poor countries. But India's laws have now changed and it may not be possible to copy new drugs in the future. And for some neglected diseases there are no good existing medicines.

### Will the multinational pharmaceutical companies object?

They will if it there is a possibility that a cheap, improved version of one of their drugs will arrive back in the UK, Europe or US where they make their profits. Then the patent lawyers will become involved.

to repackage the drug, making it less toxic but just as effective and cheaper. "It has a long way to go, but it is an exciting concept which is already demonstrated with hepatitis C. Cost is one of the key issues. If patients and health services can't afford it, a potentially good formulation can't be used."

Reformulating a drug was a classic way for multinational pharmaceutical companies to extend the life of a medicine reaching the end of its patent life, he added.

The multinational drug companies already fight bitter battles over their patent rights. Lawyers for the drug giants will take a close interest in any new drug that could potentially damage their profits. The cheap HIV drugs used in Africa are generic copies which it is illegal to bring into Europe or the US, but if ethical pharmaceuticals were licensed as new medicines, they could be sold here.

The Association of the British Pharmaceutical Industry said the key question was whether the new drug was truly innovative. "The issue

"If [new hepatitis C treatment] works in India it will eventually come back to the NHS"

Prof Shaunak

is around whether he [the researcher] has developed a novel compound which is therefore not covered by the patent on any other product," said Ben Hayes of the ABPI. "Then he or anybody else has the right to patent it." They would, however, still face the considerable challenge and expense of clinical trials before the drug could be licensed first in India and then in the UK. Only then could the NHS consider whether it was worth prescribing, he said.

A spokesman for Roche said yesterday: "Roche is committed to ensuring that as many people as possible can gain access to our medicines, many of which have transformed once deadly diseases into manageable and or even curable conditions. One such example is our commitment to supply HIV drugs to Africa on a not-for-profit basis. It costs the pharmaceutical industry on average £550m to develop a single new medicine. Patents are in place to ensure we have the resources to continue to discover cutting edge advances in the future."

