



# health bulletin

MAY 2005

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## INTRODUCTION

Welcome to the CNE Health Monthly Bulletin. Our aim is to keep readers informed of important healthcare news and publications each month. Each bulletin will have a feature of the month and then summaries of news from around Europe and further afield where relevant. Comparative studies and journal articles will also be included, as too recent and forthcoming seminars and conferences.

We would like this to be as complete as possible, so if you would like to draw our attention to interesting news and thoughts, please do! Please email them to [healthletter@cne.org](mailto:healthletter@cne.org). Thanks in advance.

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## EUROPEAN HEALTH NEWS ROUNDUP

EU, UK, Pharmaceutical News

### News from the EU

- + 'Europe is a "second class continent" for Cancer Research – *British Medical Journal*
- + 'Brussels hopes extra research money will aid innovation' - *Financial Times* (05/04/05)
- + Cross-border trade in medicines causes concern in the EU – *The Lancet*, 08/04/05
- + 'Lagging Behind Again' – Helen Disney, CNEHealth.org

### 'Europe is a "second-class continent" for cancer research' – *British Medical Journal*

Funding for cancer research in the European Union lags far behind that in the United States and varies enormously from one EU country to another, a new survey by the European Cancer Research Managers Forum shows.

Produced with the support of the European Commission, the survey is the first comprehensive analysis of cancer research funding in Europe. It identified 139 sources of non-commercial financing that provided 1.43bn (£1bn; \$1.9bn) in 2002-3.

The investigation by the forum, which was set up in 2001 to promote networking and cooperation among national funding bodies and strategic decision makers, showed that the gap between the EU and the United States in this area is much wider than originally thought. US per capita spending (17.63) is seven times that in the EU (2.56), and its spending as a percentage of gross domestic product is four times that in the EU.

Commenting on the finding, Richard Sullivan, the forum's chairman, said: "This gap is a substantial threat to the ability of the EU to translate cancer research into patient benefit."

The discrepancies are even more marked between countries in the EU. In the study period (2002-3) the

country that spent the most was the United Kingdom (388m), while Malta spent nothing. Britain also leads when funding is expressed as a percentage of gross domestic product, followed by Sweden, Germany, France, and the Netherlands.

The survey shows that the EU concentrates much of its spending on basic research, at the expense of preventive and clinical research. Biology receives 41% of all cancer research funding, compared with 20% for treatment and 4% for prevention. The corresponding figures in the US are 25%, 25%, and 9%.

Gordon McVie, senior consultant to the European Institute of Oncology in Milan, described the findings as "a clarion call" to the European Commission, which awarded around 90m to research in this area, to increase its funding. "The survey shows that Europe is a second class continent in terms of cancer research funding," he said.

<http://bmj.bmjournals.com/cgi/content/full/330/7494/746-b>

### 'Brussels hopes extra research money will aid innovation' – *Financial Times*, 05/04/05

The European Commission will this week set out plans to double its research budget to €70bn (\$90bn, £48bn) as it seeks to bolster growth and competitiveness and catch up with the US and Japan's spending on innovation.

The seven-year blueprint for research and development, to be launched on Thursday, will underline plans to help transform the European Union into a "knowledge-based" economy that will deliver a new range of high-tech innovations. The plans will be scrutinised by industry and universities keen for indications of the EU's priority areas for funding research between 2007-2013.



Boosting R&D is central to the EU's fading effort to become the world's most competitive economy by 2010. The 25-country bloc lags behind the US and Japan on the share of national income spent on R&D and is suffering from a brain drain of researchers away from the EU. Under the plans, the European Commission will give details of 10 themes on which research will be based. These include projects on health, nano-science, energy, information technology and space. They will also set out details of an autonomous European Research Council, made up of scientists, to promote excellence and help small teams of researchers get smoother access to the proposed €10bn of grants available each year.

EU countries have made scant progress on their pledges to increase public and private investment in research to 3 per cent of GDP by 2010. EU spending on R&D is only 1.93 per cent a year, far behind the US and Japan, which invest 2.76 and 3.12 per cent respectively. The Commission will outline efforts to deliver results, simplify applications for grants, improve career prospects for researchers, enhance collaboration with countries outside the EU and boost the role of SMEs. It will also push for more public-private collaboration. But the proposals have caused alarm in some EU countries, concerned that the drive for results will mean EU money is pumped into elite institutions with the best research records -mainly in Britain, the Nordic countries and the Netherlands. The plans also involve "poles of excellence" - the development of expertise in a particular subject that will attract researchers and money from the EU and beyond.

The Commission estimates that the doubling of funds will lead to a 0.96 per cent increase in economic growth by 2030 and nearly 1m more jobs. Some of the potential projects the Commission is expected to outline include work on diseases such as malaria and tuberculosis, research on the brain and ageing, creating new "nano" products, work on climate change and hydrogen and creating software communications networks and satellite projects.

<http://news.ft.com/cms/s/ea275938-a4a5-11d9-9778-00000e2511c8.html>

## **Cross-border trade in medicines causes concern in the EU – *The Lancet*, 08/04/05**

Patients from rich European countries are taking advantage of the EU's open borders to stock up on cheaper medicines from neighbouring countries. But while this practice is often financially beneficial, critics warn that patients are putting themselves at risk. Katka Krosnar reports.

German patients are travelling to the Czech Republic in increasing numbers to buy over-the-counter drugs. And pharmaceutical companies are becoming concerned that the varying prices of medicines across the Europe are to blame, after the latest reports of this practice emerged in February. In most of the 10 new member states that joined the EU last May, drugs are significantly cheaper than in the older western European countries--a situation that reflects their citizens' lower spending power. But critics warn that this practice is risky for patients who must buy drugs from unfamiliar locations, and that it will put pressure on governments to adopt uniform pricing policies, which will disadvantage individuals in poorer EU states.

Czech pharmacies charge significantly less than their German counterparts for certain over-the-counter drugs--for example, the painkiller ibuprofen is 10 times cheaper in the Czech Republic than in Germany. For this reason, many German citizens are taking advantage of the newly open borders and are travelling abroad to stock up on treatments. In some Czech towns, the practice has become so common that queues of German customers form outside pharmacies to wait for them to re-open after the lunch break. Some German companies are even buying medicine at Czech prices and selling them for more in Germany.

In addition to purchasing over-the-counter drugs, patients from any of the 25 EU nations can theoretically present their prescriptions to pharmacies in any of the other member states. Lubomir Chudoba, head of the Czech Pharmacists' Chamber, predicts that this type of cross-border trade will grow. "With additional payments of around E8 in Germany for issuing a prescription, and none in the Czech Republic, it's quite logical that more patients will come to cheaper countries like the Czech Republic for prescriptions", he says.

"Some pharmacies in border regions have reported sales of some over-the-counter medicines are up



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100% after the country's EU accession and that must be due to cross-border trade. It's a good thing for these pharmacies as it increases their business and it's not going to create any problems in terms of supplies as they are always able to react to changes in stock levels", he says.

However, says Chudoba, this trend is also a concern. He says that acquiring prescription medicines in a different country to the one where the prescription was issued could lead to fraud because it can be very difficult for a pharmacist in one country to judge whether or not a prescription issued in another country is genuine. "For example", explains Chudoba, "Czech pharmacists would struggle to know what a Finnish prescription looked like."

But Christophe de Callatay, spokesman for the European Federation of Pharmaceutical Industries Association (EFPIA) disagrees. He believes the main concern about cross-border buying is the damage it will do to medicine stocks. "This practice could ultimately result in shortages in the source country", he says.

Panos Kanavos of London's School of Economics, who has written papers on parallel trade, insists that the comprehensive coverage of Europe's health-care systems mean there is little incentive for patients to take risks in other countries. "Of course with the principle of free movement of trade you can't stop patients buying drugs abroad, but I don't see this happening to a large extent", he says.

However, the recent reports of cross-border buying are enough to worry pharmaceutical companies, which remain concerned about the expansion of parallel trade--where goods are bought and sold outside the the official distribution system. Drug price differences between member states mean traders can make profits by buying medicines from cheap countries and selling them on at a profit. Spain and Greece are popular source countries for parallel traders.

Matthew Worrall, spokesman for the Association of the British Pharmaceutical Industry (ABPI), says it is still too early to know the full effect of EU expansion on parallel trade. "It takes time for traders to get set up in a new market and even then it takes several quarters' figures before we would notice any new trend. I think you can make some reasonable assumptions based on the pharmaceutical prices in

the new EU nations--the bigger the disparity, the more margin a parallel trader stands to make, the more attractive a market it is", he says.

National governments in Europe set pharmaceutical prices, so the costs of drugs are therefore a reflection of government priorities. "Some [governments] opt for the cheapest health service possible", explains Worrall, "but others, like the UK, acknowledge the cost of research and development and set prices to encourage companies to develop further medicines." Parallel trade, although perfectly legal, undermines this arrangement and, Worrall adds, "gives profit margins not to companies investing in research, but to entrepreneurs investing in warehouses and white vans".

Pavol Mazan, executive director of the International Pharmaceutical Companies Association in the Czech Republic, says a large number of companies are already applying for parallel trade licences in the country. "There are several dozen submissions from parallel traders interested in exporting medicines from the Czech Republic to other EU countries where they can sell the medicines for higher prices. At the moment these traders are getting orientated and are studying the price comparison differences to see how such business could be implemented, but I expect parallel trade to grow", he says.

The EFPIA estimates that parallel trade is costing pharmaceutical companies E5 billion in lost sales and around E2 billion in lost profits annually. Although Kanavos points out that the exact cost is difficult to calculate due to the problem of determining how much is parallel trade. Mazan says international pharmaceutical companies in countries like the Czech Republic, where average salaries are around one-sixth of western Europe, are struggling to keep drugs affordable for patients while reducing the risk of parallel trade.

"There is pressure to keep prices down to reflect spending power but that leaves the door open to parallel traders. Companies are suffering because they are losing income, which could be spent on research and development. I would say it's a huge problem", he says. Mazan is also concerned that this practice could lead to shortages of medicine for patients. "It is well-known that Greece, a typical source country, experiences shortages from time to time--the same could happen in a country like the Czech Republic", he adds.



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According to the EFPIA, patients are taking a risk if they indulge in cross-border buying because the quality of medicines bought and sold outside the traditional system cannot be assured. It also warns that patients buying medicine across the border will most likely have instructions in a foreign language. "You cannot assume that patients are aware of the risks that they may be exposed to by buying from unfamiliar locations", De Callatay adds. With patients fully covered by health systems in their own countries Kanavos argues they reap no benefits from parallel trade. "There is no benefit directly to patients from parallel trade because of the way we structure core payments", he says. The ABPI concurs, saying that Britain's National Health Service gains little financially from the use of parallel imports and that the practice can also lead to confusion among patients about the packaging. "The only ones to really benefit from parallel trade are the parallel traders and also pharmacies, although there are modest savings to health insurance organisations through direct price effects", Kanavos adds.

De Callatay says there is no legal basis for either setting limits to pricing differences for the same medicines or pricing medicines according to spending power levels. "Flexibility within the single market would be greatly improved if companies had a basic right to launch medicines after technical approval and a clearer distinction between the prescriptions provided through national solidarity-based health systems and those that trade in the transnational market", he says.

<http://www.thelancet.com/journal/vol365/iss9467/full/lan.365.9467.analysis.and.interpretation.32962.1>

## **Lagging Behind Again' – Helen Disney, CNEHealth.org**

The International Herald Tribune recently ran an [interesting article](#) by former Swedish Prime Minister Carl Bildt arguing that, despite efforts by Jose Manuel Barroso to revive the flagging Lisbon agenda, Europe is still lagging behind the USA when it comes to research and development, especially in the health sector. As he rightly points out:

"Look at the pharmaceutical industry. In 1980, 80 percent of all new drugs were developed in Europe; today the United States supplies 80 percent of the world's new medicine. Unless Europe makes a

determined effort to reverse this relative decline, by 2012 U.S. spending on pharmaceutical research and development will be twice the size of total European spending.

Not only does the pharmaceutical case give us a feel for the size of the challenge Europe faces in closing the trans-Atlantic competitiveness gap, it also highlights some of the obvious causes of what European Trade Commissioner Peter Mandelson recently called "Europe's relative decline vis-à-vis the rest of the world."

At this critical time, however, the EU Commission seems to lack the necessary political courage to stop the exodus of pharmaceutical research facilities."

## **News from the UK**

- + Pill 'could lead to longer lives' – BBC News, 31/03/05
- + Drugs watchdog failing patients, warns report – *Financial Times*, 05/04/05
- + 'Drugs industry suffers drop in research' – *Financial Times*, 06/04/05

## **Pill 'could lead to longer lives' – BBC News, 31/03/05**

People could one day extend their lifespan by up to 30 years by taking a pill, a scientist has claimed. Professor John Speakman, from Aberdeen University, said the hormone thyroxine could boost metabolism and so lifespan. He said tests on mice suggested, if the right dose could be identified, humans who would otherwise have died aged 70 could live to 100. But a leading hormone specialist warned too much thyroxine could cause potentially fatal health problems. Studies carried out by the UK team showed the mice with the highest metabolic rate lived around 25% longer than those with the lowest. Professor Speakman said this would translate to a difference of around 30 years in humans. When mice were given thyroxine, they had increased metabolic rates and lived longer, compared with animals which were not given the hormone. Thyroxine is already given to people who do not produce enough of the hormone naturally, so that they have a healthy metabolic rate. But people with too much thyroxine in their bodies also



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have to take medication to bring their level back to normal.

## 'Longer lives'

Thyroxine boosts the body's metabolic rate which has a beneficial effect on cell biology, setting off a process which reduces the production of damaging free radicals. Professor Speakman, who has been awarded a £450,000 grant by the Biotechnology and Biological Sciences Council, said: "We know thyroxine affects your metabolic rate. The key is getting the right dose." He will now carry out research with mice to determine the most effective dose of the drug. Professor Speakman said it might not be possible to find a level that did not have detrimental effects on human health. But he said there were other molecules which could have the same effect on uncoupling proteins.

## 'Not true for humans'

Professor Speakman said: "The end point of this research is the hope we'll be able to give people extra healthy years. We don't want to extend their stay in a nursing home." His work is set to be published in the *Journal of Experimental Biology*. However, a leading specialist in human hormone disorders said the findings would "not be true for humans". Dr Pierre Bouloux, an endocrinologist at the Royal Free Hospital in London, said: "This is an example of research being extrapolated on the basis that a mouse represents the best model for a man. It doesn't. "Mice have a different metabolism to humans." He added: "Having an over-active thyroid gland puts you at a three-fold risk of potentially fatal heart disorders and a three to four-fold risk of osteoporosis. "An over-active thyroid causes considerable morbidity in the ageing population." And he warned people who had even a slightly higher level of thyroxine were at risk of ill health.

<http://news.bbc.co.uk/1/hi/health/4396495.stm>

## **'Drugs watchdog failing patients, warns report' – *Financial Times*, 05/04/05**

Tougher regulation of the pharmaceuticals industry is needed, with the risks of new drugs investigated properly before they are prescribed, MPs said today. The Commons health committee called for an urgent review of the Medicines and Healthcare products

Regulatory Agency, saying the watchdog lacked "the discipline and leadership needed to protect patients' health needs".

Its recommendations follow its hearings last year amid growing concerns about the side effects of drugs including Seroxat, an anti-depressant, and Vioxx, an anti-inflammatory medicine. It also comes at a time of widespread international debate about regulation, with industry critics concerned that new drugs are being aggressively marketed with insufficient regard to the health risks. "The pharmaceutical industry is extremely powerful and influences healthcare at every level," said David Hinchliffe, the committee chairman, in written remarks. "We have developed an over-reliance on medicines. They have been over-prescribed and patients have suffered as a result."

The committee called for systematic public inquiries whenever a drug was withdrawn on health grounds and for responsibility for pharmaceutical companies to be shifted from the Department of Health to the Department of Trade and Industry. They also said the MHRA, which comes under the remit of the health department, should be made more independent from industry and government. The lack of transparency in the funding by drug companies' of patient groups, which advocate the use of new treatments, was also attacked. Doctors, the report added, "are sometimes too willing to accept hospitality from the industry and act uncritically on the information" it supplies. In remarks likely to irritate the pharmaceutical industry, the committee said the clinical trials system "provides ample opportunities for bias" and warned of the large number of costly "me-too" drugs introduced with no significant additional health benefits.

Comparative clinical trials should be more widely used by companies, with new drugs compared with existing drugs in the same treatment class before they were approved, to see whether they were more effective. This conclusion comes as drug company executives are calling instead for a shift from the European system of comparative trials in favour of more US-style testing of new drugs against placebos.

However, the committee called for a switch towards the approach of the US Food and Drug Administration, the MHRA's counterpart, in holding earlier consultation with pharmaceutical groups to co-ordinate the nature of clinical trials to be carried out. The report was met with a guarded welcome by the government, industry and consumer bodies. Lord



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Warner, the health minister, said the government would "carefully consider the recommendations", while stressing that the MHRA had a strong reputation. The MHRA, created from the merger of two regulatory bodies, has recently unveiled plans for a more open system of "yellow card" warnings by which patients and medical practitioners can alert it to adverse reactions to drugs.

Earlier this year it overhauled its advertising codes in a procedure designed to take a tougher and more targeted approach to abuses of marketing rules. In addition, the Association of the British Pharmaceutical Industry, with its international counterparts, has unveiled a voluntary system designed to make publicly available all clinical trials when they are begun, and to publish their results once concluded. Richard Barker, director-general of the ABPI, welcomed the report's calls for improved information to patients on new medicines, better reporting of side effects, moves towards public registers of funding of patients groups and financial benefits received by doctors, and mandatory post-graduate training for prescribers.

But he warned of a number of "fundamental misconceptions" and questioned the committee's analysis of the growing use of medicines, stressing that the UK had one of the lowest and slowest uptakes of innovative treatments in Europe.

\* The procurement system for medical devices is risk-adverse, operates under high cost-cutting constraints and is not adapted to evaluate and acknowledge the benefits of new products, according to a study by Arthur D Little, the consultancy, for the DTI. It called for greater transparency in the evaluation of new products through clinical trials.

<http://news.ft.com/cms/s/d735f03a-a56f-11d9-8616-00000e2511c8.html>

**'Drugs industry suffers drop in research'**-  
*Financial Times, 06/04/05*

Research and development expenditure on pharmaceuticals dipped in 2003 and capital investment fell more sharply, the Association of the British Pharmaceutical Industry said yesterday. Britain's trade balance in pharmaceuticals also fell slightly from £3.6bn in 2002 to £3.4bn in 2003, despite record exports of £12.2bn.

The figures might be no more than "a blip", said Richard Barker, the ABPI's director-general, producing the trade association's annual review. But, he added: "We need to ensure that they do not become a sustained fall." R&D expenditure in 2003 - the last year for which there are full figures - slipped to £3.24bn from £3.3bn the previous year.

Capital expenditure fell more sharply to £753m from £929m, reaching its lowest level in cash terms since 1997. The five-year average since 1999 was £925m, with the association saying it has not been able to identify a similar decline in 2003 among large competitors. The ABPI said it was not easy to identify reasons for the falls but cited a series of issues that posed threats to Britain's future as a pharmaceutical research centre in the face of mounting competition from China, India and eastern Europe, as well as more traditional competitors in the US and Organisation for Economic Co-operation and Development. Attacks on workers and companies from animal extremists continued to pose a threat to investment, the industry said. The number of reports of damage to property was up from 830 in 2002 to 1,077 last year, while abusive phone calls were up to 108 from 23 in 2002.

Mr Barker said: "We are also seeing an erosion in the science base in universities", with chemistry courses closing, companies complaining about the quality of graduates, and too few doctors training in clinical pharmacology. Companies were increasingly importing science graduates from overseas. And while National Health Service expenditure on medicines had risen from £7bn in 2000 to more than £10.6bn last year, the percentage of its budget spent on pharmaceuticals remained constant at 12.5 per cent. Too few of the National Institute for Health and Clinical Institute's recommendations for the uptake of new drugs were translating into a swift rise in sales and the UK continued to take up new products more slowly than many other countries.

Vincent Lawton, the ABPI's president, was careful to say that "the UK-based industry remains highly successful", with about a quarter of the world's top 100 prescription medicines developed in the UK. A recent 7 per cent cut in prices to the NHS had been balanced by higher allowances for research and development. Government action to extend clinical trials in the NHS was also welcome, he said. But costs were now so much lower in eastern Europe as well as



in India and China - both of which had an "exploding" science base - that the dangers of losing out to other countries were very real.

<http://news.ft.com/cms/s/9a3f3324-a639-11d9-b67b-00000e2511c8.html>

## Pharmaceutical News

- + 'Incentivising Research & Development for the Diseases of Poverty' – International Policy Network Working Paper
- + A new way of developing drugs for neglected diseases of the poor world – *The Economist*, 18/04/05
- + *Lancet* direct-to-consumer advertising
- + 'The Scum of the Earth' – Bioprospecting in *The Economist*, 07/04/05

### 'Incentivising Research & Development for the Diseases of Poverty' – International Policy Network Working Paper

Although many of the world's health problems could be solved if available medicines were properly distributed, there is certainly a need for new and better drugs to fight the diseases of poverty. This paper critically surveys the various methods proposed that hope to incentivise R&D for these diseases, whilst arguing that wealth creation is the only route to self-sustaining healthcare systems that effectively drive demand for new drugs.

<http://www.policynetwork.net/uploaded/pdf/IncentivisingRD.pdf>

### A new way of developing drugs for neglected diseases of the poor world – *The Economist*, 18/04/05

THIS week, scientists from the Institute for OneWorld Health, the first not-for-profit pharmaceutical company in America, presented the results of a large clinical trial at the Third World Congress on Leishmaniasis in Palermo, Italy. Leishmaniasis is a parasitic infection transmitted by the bite of a sand fly. The trial shows that an antibiotic called paromomycin is effective for treating the most dangerous version of the disease, visceral leishmaniasis, which affects 1.5m people around the world and kills 200,000 of them every year. Those data are obviously important for medical

reasons. But they are also important as a demonstration that the institute's novel approach to drug development is working.

About 90% of the planet's disease burden falls on the developing world. Yet only 3% of the research and development expenditure of the pharmaceutical industry is directed toward those ailments. The rest goes towards treating diseases of the rich. In 2000, Victoria Hale (pictured above), founded the institute to help tackle that discrepancy. She knew from her work as a scientist in the pharmaceutical and biotechnology industries, and subsequently as an official at America's Food and Drug Administration, that numerous promising drug-development projects—particularly for diseases of the poor—are dropped for lack of funding. She reasoned that there was a gap in the market, between academically inclined university departments and fully fledged pharmaceutical firms, for an organisation that would identify such orphans, get their owners to donate the intellectual property if they were still in patent, raise development funding from non-commercial sources, and arm-twist researchers to contribute their expertise to the development process pro bono.

The Institute for OneWorld Health, founded by Victoria Hale, announces clinical trial results and research projects. The WHO gives information and links on leishmaniasis, Chagas disease, schistosomiasis and diarrhoea. See also the Third World Congress, Celera Genomics, Yale University, University of California, Santa Barbara, the Bill & Melinda Gates Foundation, the Food and Drug Administration and Lehman Brothers.

So far, the donation side seems to have worked. In 2002 Celera Genomics gave the institute a promising compound for the treatment of Chagas disease, which infects 12m people in Latin America and is an important cause of heart failure in the region. Yale University has also licensed a potential drug for Chagas to the institute. And the University of California, Santa Barbara, gave it a compound intended for the treatment of schistosomiasis, which affects 200m people, mostly in sub-Saharan Africa. The compound the institute has pushed furthest, though, is paromomycin. In this case no donation was needed, as the drug's patent has expired. Indeed, it is currently used for the treatment of a variety of parasites. But it has never been properly road-tested for leishmaniasis.



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## Trials and tribulations

Visceral leishmaniasis occurs predominantly in Bangladesh, Brazil, India, Nepal and Sudan. Its symptoms include fever, weight loss, enlargement of the spleen and liver, and anaemia. Several drugs to treat it are available, but their usefulness is limited either because the parasites have evolved resistance to them, or because they are too expensive.

In the mid-1990s, the World Health Organisation (WHO) started testing an injectable form of paromomycin as a treatment for visceral leishmaniasis. Its researchers completed small-scale trials which demonstrated that the drug was safe for use against the disease and seemed to cure the infection. But development stalled at that point because the WHO was unable to find a sponsor for a large-scale trial that would have compared paromomycin with existing treatments.

In 2001, Dr Hale approached the WHO about taking over the trials. The WHO agreed, the Bill and Melinda Gates Foundation stumped up the money, and the institute teamed up with four health-care centres in the Indian state of Bihar in order to test the drug against amphotericin B, an established but expensive treatment.

The trial showed that the two drugs worked more or less equally well. In both cases, 99% of patients responded within four weeks—and though slightly fewer of those on paromomycin remained uninfected after six months, all those relapses proved treatable by other drugs. Given that a course of amphotericin B costs \$120, while the institute reckons a course of paromomycin will come in at around \$10, this seems a reasonable trade-off. The institute, supported by a further donation from the Gates foundation, plans to submit an application for regulatory approval to the Indian health ministry by the end of the year. If that is granted, the manufacturing will be done by Gland Pharma, a drug company based in Hyderabad.

Having shown its approach can work, the institute's next target is diarrhoea, which kills 2m people a year, most of them children, by dehydrating them. In this case, the Lehman Brothers Foundation is providing the money.

Diarrhoea is a symptom, rather than a disease. Indeed, it has eight common causes in the tropics (four bacteria, three viruses and a protozoan). Instead

of scattering its efforts among these causes, the institute's researchers are sifting through orphan compounds that might attack dehydration directly, by stopping the secretion of water into the gut. Such a drug would augment oral rehydration therapy—a combination of salt and sugars mixed into water that is the standard regimen used in the developing world. Diarrhoea is hardly the most glamorous condition it is possible to work on. But if Dr Hale and her institute can find a treatment for it among other people's discards, they will truly have turned base metal into gold.

## **Lancet calls for limits on direct-to-consumer Advertising**

In a recent editorial, *The Lancet*, a long-standing British medical journal, argued that direct-to-consumer advertising should focus equally on the risks as well as the benefits of pharmaceutical. 'In the wake of the recent uproar over rofecoxib (Vioxx) and valdecoxib (Bextra), in which direct-to-consumer (DTC) advertising of prescription drugs spurred millions of people to take cyclooxygenase-2 (COX-2) inhibitors even when they were not indicated, one drug company is changing the tone of its advertising campaigns.

Last week Johnson & Johnson became the first company to create a more cautious, safety-oriented advertisement with more emphasis on drug risks and side-effects. One such advertisement, for a birth-control patch, shows a doctor curbing a young woman's immediate enthusiasm for the product. The doctor warns her about the risk of stroke, advises her not to smoke, and tells her to consult with her own doctor about whether the product is advisable for her.

DTC print advertising was introduced in the USA more than 20 years ago, and television advertisements followed in the late 1990s. Before Johnson & Johnson's innovation, drug risks and side-effects were announced at the end of the commercial, often by a narrator reading off lists of complications at fast speed. Presented in this bizarre fashion, the information was virtually unintelligible to listeners, but was ripe for parody by satirists and comedians.

Did the COX-2 controversy suddenly cause the drug companies to take a harder look at their responsibilities to patients? Perhaps. Then again, threats by the US Food and Drug Administration of more stringent monitoring of the content of DTC advertisements, and pending legislation in four states



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that would curtail or ban DTC advertising outright might have had influence.

And there is some evidence that consumers have become jaded with print and television advertisements (the internet remains the great frontier). But whatever finally pushed drug companies to acknowledge that selling prescription drugs is not just like selling any other product, their new-found enthusiasm for providing more risk information to patients marks a sound correction to an out-of-control situation. Others ought to follow Johnson & Johnson's lead, as should manufacturers of diagnostic tests and devices, who are now beginning their own DTC campaigns.'

## 'The Scum of the Earth' – Bioprospecting in *The Economist*, 07/04/05

### Searching for drugs in a tropical country

For William Gerwick, nature's bounty is to be found in a pot of pond scum. Organisms that cannot run away from their predators (plants and coral, for example, as well as the micro-organisms that make up scum) experience a strong evolutionary pressure to become poisonous. But one creature's poison is another's drug. And the more species there are in a place (in other words, the higher its biodiversity), the better the chance is of finding something pharmacologically useful there. So for Dr Gerwick, a pharmacologist from Oregon State University who works in Panama (one of the most biodiverse places on the planet) the local scum is a particularly promising raw material.

Dr Gerwick is a member of an organisation called the International Co-operative Biodiversity Groups (ICBG), which seeks applications for knowledge about biodiversity. Thanks to his collaboration with another ICBG member, Eduardo Ortega, a parasitologist at Panama's Institute for Advanced Scientific Investigations, he has discovered that the scum (or, rather, the cyanobacteria of which it is composed) does indeed contain potential drugs. Dr Ortega's contribution has been to come up with a clever way of testing whether the organisms Dr Gerwick and others find on their expeditions are plausible candidates for the treatment of disease.

When the ICBG project started seven years ago, it focused on treating tropical infections such as malaria. Unfortunately, the equipment needed to test its discoveries for antiparasitic activity was difficult to import. In particular, the standard assay for malaria involved the use of radioactive materials, which western governments were reluctant to see end up in a poor country with a chequered political history. Dr

Ortega, therefore, invented a new assay that did not involve radioactivity.

The new method works by tagging a parasite's DNA with a fluorescent stain. The parasites are then incubated in an appropriate medium (in the case of malaria, red blood cells) and extract-of-scum, or coral, or whatever, is added. In the absence of the extract, the parasites grow and the sample becomes more fluorescent. But if the extract stops the parasites reproducing or—better still—kills them, that does not happen. The researchers then know they have found something of interest.

At the moment, they are using this method to test their finds for activity against leishmaniasis, malaria and, most recently, dengue fever. So far, a number of promising leads have been discovered, including a cyanobacterium with a very high activity against malaria. And although no drugs are in development as yet, if the researchers do find one, there is already a plan for how to divide the spoils.

Who should benefit from patents based on poor-world biodiversity is a ticklish political problem. On the one hand, that biodiversity is surely the patrimony of the country in question (no one would be arguing the point if the resource were, say, a mineral reserve). On the other, the hard work of turning a raw biological discovery into a marketable product is usually done in a rich country, and patent law prefers to protect the person who reduces an idea to workable practice. In this case, though, the answer is simpler than usual, as both biodiversity and research are located in the same country. Dr Ortega says that at least 50% of any profits the team receives will go into environmental trust funds, while the rest goes to the institutions that have supported the project, including the University of Panama.

The two researchers also believe that even though no drugs have yet been developed, the project has been a success. The fluorescence test is now used in other developing countries, including Bolivia and Madagascar, and will be included in a drug-discovery kit being created by America's National Cancer Institute. In addition, the project is a training ground for Panamanian scientists.

It may even have conservation benefits. According to Todd Capson, the ICBG's co-ordinator in Panama, the island of Coiba off the country's Pacific coast has been saved from developers thanks to the ICBG's



finding that a newly discovered coral species which lives there has powerful antimalarial properties. The island is now to become a nature reserve, in order to protect the species. In this case, coral turns out to be more valuable than hotels and golf courses.

[http://www.economist.com/printedition/PrinterFriendly.cfm?Story\\_ID=3839781](http://www.economist.com/printedition/PrinterFriendly.cfm?Story_ID=3839781)

## CONFERENCES, EVENTS AND PUBLICATIONS

### Upcoming Events in Europe

- + **14-15<sup>th</sup> June:** 1<sup>st</sup> Annual Obesity Europe Conference (Brussels)
- + **15 June:** Healthcare Consumer Summit – Health Consumer Powerhouse (Brussels)
- + **28th June:** Global Development Summit – International Policy Network (London)

#### 1<sup>st</sup> Annual Obesity Europe Conference

The **1st Annual Obesity Europe Conference** will be held at the Sofitel Astoria Hotel, Brussels, on the 14th-15th June, 2005. The event brings together a selection of the top experts and decision makers from Europe and beyond as well as high-level industry representatives, to facilitate a rational debate on the cross-sector strategies required to tackle European obesity.

The conference will explore in detail the issues surrounding the proposed legislation on food and nutritional labelling, and will offer attendees the opportunity to gain an insight into the priorities of the UK Government during their forthcoming Presidency of the EU.

Confirmed speakers include **Melanie Johnson MP**, British Minister for Health, **Jules Maaten MEP**, EU Shadow rapporteur for draft regulation on Nutrition and Health Claims, and **Dr Marie-Laure Frelut**, Chair of the European Action Group on Childhood Obesity.

For further information and to register for this conference, please go to <http://www.obesityeurope.com>. Alternatively, please call the conference team on +44 (0) 2920 642 701 / 704.

#### Health Consumer Summit – Health Consumer Powerhouse

The Health Consumer Powerhouse will host its first Health Consumer Summit on June 15<sup>th</sup> in Brussels. The summit will bring together creative and influential consumer advocates from around the EU, and will feature **Christofer Fjellner MEP** and **EU Health Commissioner Markos Kyprianou** (TBC). **Johan Hjertqvist**, President of the Health Consumer Powerhouse, will also present the HCP's vision of the era of the health consumer.

Visit the Health Consumer Powerhouse website – [www.healthpowerhouse.com](http://www.healthpowerhouse.com)

#### Global Development Summit – International Policy Network

In the run-up to the G8 Summit in July, certain rock stars, celebrities and NGOs are calling for an increase in foreign 'aid', 'relief' from government debt, and trade 'justice'. But would such policies actually achieve their good intentions?

Speakers at the Global Development Summit will discuss the real barriers to the elimination of poverty.

Register to receive more information at [www.globaldevelopmentsummit.org](http://www.globaldevelopmentsummit.org)