Eli Lilly pays record fines of $1.4bn for promoting off-label use of olanzapine for common disorders

Zosia Kmielowicz LONDON

The drug giant Eli Lilly has agreed to pay $1.4bn (£1bn; €1.1bn) in settlement for the marketing of its antipsychotic drug olanzapine (Zyprexa) for off-label uses. It is the largest individual corporate fine in history.

The company began its promotion by encouraging doctors who treated people in nursing homes and assisted care facilities to prescribe olanzapine, because one of the drug's side effects is sedation. It claimed that “this side effect was a therapeutic benefit, not an adverse event.” The sales force used the slogan “5 at 5,” meaning that 5 mg of olanzapine at 5 pm would help patients sleep, said the department’s statement.

Eli Lilly expanded its “illegal” marketing strategy to primary care doctors in 2000 with the “Viva Zyprexa” campaign, whose goal, the statement said, was to make the drug “an everyday agent in primary care, even though the company recognized that schizophrenia and bipolar disorder were not viewed as conditions typically treated by primary care physicians.”

The department said that the off-label marketing campaign “raised safety issues and posed potential risk to patients.”

Eli Lilly knew that olanzapine could cause significant weight gain and obesity and increase the risk of hyperglycaemia and diabetes, “yet despite written caution from the FDA [US Food and Drug Administration], Eli Lilly continued to promote these adverse events as therapeutic benefits of Zyprexa use, particularly in the elderly.”

The statement added, “Eli Lilly’s management created marketing materials promoting Zyprexa for off-label uses [and] trained its sales force to disregard the law.

Eli Lilly pleaded guilty to one misdemeanor violation of the Food, Drug, and Cosmetic Act and agreed to pay a total of $615m.

In a separate civil settlement agreement Eli Lilly agreed to pay nearly $800m to the US government and to state Medicaid programmes for payment for unapproved off-label uses of olanzapine.

Four former sales representatives who blew the whistle on Eli Lilly for the off-label practices and who were either fired or resigned filed lawsuits against the company. They will share $80m of the civil settlement, in a bid to encourage whistleblowers. Federal law permits whistleblowers to share in the money recovered.

John C Lechleiter, chairman, president, and chief executive officer of Eli Lilly, said in a statement, “We deeply regret the past actions covered by the misdemeanor plea. At Lilly we take seriously our responsibilities to abide by all the laws governing our business practices, and we realize that we have a tremendous responsibility to the patients and healthcare professionals we serve. Every day and with every interaction we strive to operate in a responsible and compliant manner.”

See page 193

Cite this as: BMJ 2009;338:b2117

Personal health budgets are to be piloted in England this summer

Jacqui Wise LONDON

The government has announced new legislation that will allow funds to be given to patients so that they can directly purchase their own healthcare services. Pilot schemes of personal health budgets are due to start this summer in selected areas in England.

The Health Bill 2009 will pass through the House of Lords over the next few months and is the next step in the implementation of the health minister Ara Darzi’s review of the NHS (BMJ 2008;337:a645).

Commenting on the bill Lord Darzi said, “Building on the experience of social care, the bill allows the further development of ways to give patients greater personalisation and control over the health care services they receive.”

The Department of Health said that there will be three broad categories of personal budget. The first is a notional personal budget where patients are given a budget constraint and are aware of the treatment options and the financial implications of their choices. The second category is when patients are allocated a real budget but this is held by an intermediary such as their GP or a care coordinator. The third is when patients are actually given cash payments and expected to purchase services themselves.

All three models are to be tested in the pilot programme, although direct payments won’t be allowed until the legislation is in place some time in 2010. Patients with long term conditions, those receiving care under the NHS continuing healthcare scheme, and users of mental health services are those likely to be included first in the pilot programmes.

The NHS Confederation’s report Personal Health Budgets is available at www.nhsconfed.org.

Cite this as: BMJ 2009;338:b2110
Palestinian doctor appeals for end to killing after losing daughters in last days of conflict

Merav Sarig JERUSALEM
A prominent Palestinian gynaecologist who works in Israel and lives in Gaza, and who is a long term supporter of Arab-Israeli coexistence, lost three daughters in air attacks on his home at the end of last week.

Ezzeldeen Abu al-Aish, a gynaecologist at Sheba Medical Center, Tel HaShomer, in central Israel, had been trapped in Gaza, where his family lives, since the Israeli offensive began three weeks ago. On the afternoon of Friday 16 January he was at home with his family in the northern Gaza Strip when the house was hit by an Israel Defense Forces shell, killing three of his eight children and a niece.

Dr Abu al-Aish, who has been giving frequent updates of the situation in Gaza to the Israeli media, has been heard on national Israeli television weeping with grief.

He telephoned Israel Channel 10 news reporter Shlomi Eldar, and for several minutes his voice was broadcast live on television, crying, “Oh God, Oh God, my daughters, my daughters, they killed them.”

Dr Abu al-Aish’s daughters and niece were aged between 13 and 20 years. A second niece was also critically injured in the shelling, while a fourth daughter and Dr Abu al-Aish’s brother were slightly injured.

The Liaison and Coordination Administration at the Erez crossing on the border with Israel decided to transfer them to Sheba hospital for medical treatment.

The Israel Defense Forces said that a preliminary investigation indicated that shots were fired at Israeli soldiers from within the building in which the Abu al-Aish family lives. The investigation is continuing.

“There are no words to describe the tragedy that befell this man, of all people, who does everything for the treatment of children,” said Professor Ze’ev Rothstein, director of the Sheba Medical Center.

During a press conference on Saturday 17 January called by Dr Abu al-Aish at Sheba hospital there was a harsh exchange between Dr Abu al-Aish and the parents of soldiers at the facility.

Reports said that the parents screamed “You’re a terrorist” at him. One woman, the mother of three soldiers, shouted, “Have you all gone mad? Why is he propagandising against Israel in a hospital where there are wounded soldiers?”

The press conference was stopped and a conciliatory meeting was held between the woman and Dr Abu al-Aish the next day.

“I appeal to the entire world so that my children will be the last ones to pay the price,” Dr Abu al-Aish told the BMJ.

“I must look forward and believe that there is hope.”

See the blog by Mark Clarfield at www.bmj.com

Cite this as: BMJ 2009;338:b213

Dr Abu al-Aish was heard on national Israeli television weeping with grief after his daughters were killed

Surgical checklist reduces complications by one third

Peter Moszynski LONDON

A study of hospitals in six WHO regions shows that the rate of serious complications after surgery fell from 11% in the baseline period to 7% after introduction of the checklist, a reduction of one third.

Deaths among inpatients after big operations fell by more than 40% (from 1.5% to 0.8%).

Data were collected from 7688 patients—3733 before the checklist was introduced and 3955 after.

The study was carried out in hospitals in rich and poor settings, including Ijara, Tanzania; Manila, Philippines; New Delhi, India; Amman, Jordan; Seattle, United States; Toronto, Canada; and London, United Kingdom. The reduction in complications was similar in rich and poor settings.

The 19 point checklist identifies three phases of an operation—before anaesthesia, before skin incision, and before the patient leaves the operating room. It is intended to “ensure the safe delivery of anaesthesia, appropriate prophylaxis against infection, effective teamwork by the operating room staff, and other essential practices in perioperative care,” such as ensuring that any known allergies have been considered, protocols are in place to deal with blood loss, and all instruments and swabs are accounted for.

“The concept of using a brief but comprehensive checklist is surprisingly new to us in surgery. Not everyone on the operating teams was happy to try it. But the results were unprecedented,” said Atul Gawande, the study’s main author and team leader for the development of the checklist.

Dr Gawande said that the results “indicate that gaps in teamwork and safety practices in surgery are substantial in countries, both rich and poor. With the annual global
Doctor seeks experts to lead fact finding mission in Gaza

Zosia Kmietowicz LONDON

The group Physicians for Human Rights-Israel has called for doctors with expertise in forensic medicine, medical crises, and public health to take part in an independent fact finding mission to Gaza after a ceasefire in the region.

The non-governmental organisation, which works to protect medical human rights of people in Israel and in the Palestinian territories occupied by Israel said that the mission would have several objectives.

It would try to learn about the weapons that caused the types of injuries seen in the Gaza Strip during Israel’s three week offensive, which started on 27 December, the extent and nature of attacks on medical facilities and teams, and difficulties experienced evacuating wounded and dead people. Also under investigation would be the impact of the assault on the health of people in the area.

The group has compiled a dossier on such cases. One man and his two sons were wounded while returning home from a field. Surrounded by Israeli forces, the family tried to call for an ambulance as one son died and the other had serious bleeding. Physicians for Human Rights-Israel was contacted by many people in Gaza during the conflict who were either shelled or caught in the crossfire and sought medical help. It has compiled a dossier on such cases.

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A spokesman for the Israeli Embassy in London said, “The Israel Defense Forces (IDF) has stressed that all the weaponry utilised by IDF follows international law and conventions.”

The Israel Defense Forces said at a press briefing at the weekend that the force had made an “impeccable effort” to avoid civilian casualties in the Gaza Strip.

See “Aid agencies face daunting humanitarian task in war ravaged Gaza” on bmj.com

Cite this as: BMJ 2009;338:b228

FDA lets drug firms distribute articles about off-label uses

Janice Hopkins Tanne NEW YORK

The US Food and Drug Administration has published guidance that allows drug and device companies to use reprints of journal articles about off-label, or unapproved, uses of their products in promotions to doctors.

By allowing distribution of peer reviewed, but off-label, studies, the FDA recognises that doctors use approved drugs and devices in unapproved situations.

A section of the Food and Drug Modernization Act that regulates distribution of articles about unapproved uses expired in September 2006, and the FDA came up with new, more liberal regulations this month, just before President George Bush left office. Although doctors were using drugs or devices off label (particularly to treat cancer), under the old rules companies were not allowed to promote these uses. The new guideline was published in the Federal Register on 13 January.

In its statement, the FDA said that it recognised the important public health and policy reasons to support “dissemination of truthful and non-misleading journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices and approved or cleared medical devices to healthcare professionals and healthcare entities.

“Once a drug or medical device has been approved or cleared by the FDA, generally, healthcare professionals may lawfully use or prescribe that product for treatment regimens that are not included in the product’s approved labelling.”

Representative Henry Waxman, a California Democrat, criticised the FDA’s ruling. He told the Associated Press news agency, “In the final hours of this administration, political appointees at the FDA have given drug companies a long coveted parting gift. This fundamentally undermines the requirement that companies prove to the FDA that each new use is safe and effective.”

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The FDA guidance is at www.fda.gov/oc/op/ goodreprint.html.

Cite this as: BMJ 2009;338:b187
UK firms sign up to display calories of their food on menus

Oona Mashta LONDON
Several UK high street food, pub, and sandwich chains will begin to display the calorie content of their food by the summer after a campaign by a food watchdog to try to provide more healthy options for consumers who eat out.

The Food Standards Agency is negotiating with the largest catering companies about the introduction of the voluntary calorie labelling scheme to make it easier for customers to choose healthier foods.

About six catering firms have signed up to the plan and are preparing to display calorie information on their food; another 40 or so are hoped to follow later.

The scheme is similar to a compulsory one adopted in New York city last year, where restaurant chains with 15 or more outlets must list calories on their menus. This has led to an average reduction of 50-100 kcal (210-420 kJ) for each food order.

The agency’s work ties in with the government’s Healthy Food Code of Good Practice, which challenges the food industry to support the public to make healthier choices to reduce rising levels of obesity and illness related to diet.

The calorie labelling scheme is the first step in what the food watchdog hopes will be a series of initiatives to encourage the catering industry to provide more healthy food outside the home.

The campaign for calorie labelling was triggered after surveys showed that the public wanted more nutritional information when they eat out.

A survey by the agency of more than 2000 people throughout the United Kingdom found that 85% were in favour of restaurants, pubs, and cafes displaying nutritional information.

The respondents wanted clear and easy to use information that they could see when they were choosing their food, for example, on the menu in a restaurant or on the menu board at a serving counter.

Most people were against the information being available only on the internet.

They also wanted more comprehensive information to be available freely elsewhere, perhaps on a separate leaflet that was automatically distributed, the agency said.

Food eaten outside the home makes up an increasingly greater proportion of people’s diet. The average person eats one in every six meals out of the home. Including snacks, men consume about a quarter of their calories eating out and women about a fifth.

Tim Smith, the agency’s chief executive, said, “Providing calorie information is supported by our consumer research and intuitively feels right too—this is the first and simplest step and can only be a good thing for all consumers.”

Cite this as: BMJ 2009;338:b182

UK is to investigate deaths in people with learning disabilities

Janet Snell LONDON
The UK government has announced that it is setting up a confidential inquiry into premature deaths among people with learning disabilities to provide evidence for clinical staff and improve commissioning.

The NHS is one of the key priorities in the Valuing People Now report, a cross-governmental strategy aimed at improving the lives of one of society’s most excluded groups.

In the report, published on Monday, the government accepts all 10 recommendations made by Jonathan Michael, former chief executive of Guy’s and St Thomas’s Hospital, after his independent inquiry last year into access to health care for people with learning disabilities.

These include the introduction of mandatory training in learning disabilities at undergraduate and postgraduate level, improved data collection, plus rigorous evaluation of services through a Public Health Observatory in learning disabilities.

And all trust boards will have to show how they have adapted their services to make them accessible to people with learning disabilities.

The care services minister Phil Hope said that Valuing People Now was “all about delivery,” with a deadline for every action point.

“It’s a very ambitious programme, and we have set some key priorities we want to happen quickly.”

He added that it was good timing for the launch of a three year learning disability strategy because of the government’s commitment to make services more personal, and it complements other initiatives such as those proposed by Ara Darzi.

New improved local learning disability partnership boards will be one of the drivers for change.


Cite this as: BMJ 2009;338:b227

Lack of funds slows

Susan Mayor LONDON
Lack of funding has prevented progress in UK stem cell research that is based on creating human-animal hybrid clones, despite legislation that allows the technique being passed a year ago, researchers warned this week.

Two of the three UK researchers who were granted licences last year to conduct research with human-animal hybrid stem cells, Stephen Minger at King’s College, London, and Lyle Armstrong at Newcastle University’s centre for life, said that they had been unable to initiate or continue with early studies because research councils had turned down grant applications.

Dr Minger, senior lecturer in stem cell biology at King’s College, London, said that the Medical Research Council had turned down an application by his department for about £1m (£1.1m; $1.5m) to cover a three year project.

The aim was to develop stem cell lines from people with genetic forms of neurodegenerative conditions, including Alzheimer’s disease, Parkinson’s disease, motor neurone disease, Parkinson’s disease, motor neurone disease,
Trusts back reading groups to boost health and wellbeing

Oona Mashta

Prescribing a good book to read aloud is an effective way to boost health and wellbeing, according to a reading charity that has won funding from primary care and mental health trusts to hold group reading sessions for patients.

The Reader Organisation, which is dedicated to promoting reading to everyone, of all ages and backgrounds, runs more than eight weekly read aloud groups for patients in general practices and hospitals throughout Merseyside.

Wirral and Liverpool Primary Care Trusts and Mersey Care Mental Health Trust are backing the organisation’s project, called “Get into reading,” which is open to patients with different medical conditions but particularly mental health problems. The organisation has been awarded about £40 000 (€44 500; $58 500) from trusts in Merseyside to train people to run reading groups for patients.

Supporters of the organisation, who include doctors as well as authors and keen readers, gathered at the Wellcome Collection Conference Centre, in London, this week to discuss the health benefits of group reading.

Dr Stephen Minger

Dr Minger admits that induced pluripotent stem cells are cheaper to produce than human-animal hybrid stem cells.

His grant application included nearly £80 000 for new micromanipulation equipment.

However, Dr Minger considered that such cells have not yet been shown to have the same potential as embryonic stem cells.

Dr Davis said that she had known a range of different patients with long term health conditions gain therapy and comfort from the groups.

Richard Horton, editor of the Lancet, said, “Reading can give you some instrument, tool, or ways, whatever you like to call it, to adapt to your own personal situation.”

Although there is a lack of evidence based research on the impact of group reading on health, supporters of the movement said that their own experiences and that of their patients firmly suggested that it was positive.

Members of the organisation don’t prescribe specific books for different conditions, but they think that novels, poetry, and biographies are better than non-fiction. Often the reading groups suggest books to read.

Louis Appleby, national director for mental health, said, “Get into reading is exactly the kind of work we at the Department of Health want to develop over the next 10 years—facing outward into the wider community and looking after the mental health and well being of the general population.”

See www.thereader.org.uk.

Cite this as: BMJ 2009;338:b163

human-animal stem cell research despite legislation in favour

and spinal muscular atrophy. The group planned to study the underlying pathophysiology of these conditions in the cells most affected.

Dr Minger thought that his grant application was turned down because the reviewers considered that it was not competitive in the face of the lack of overall funding for medical research in the United Kingdom, and in comparison to the costs of funding other types of stem cell research.

“The three reviewers said they thought there was merit in our application but questioned the need for using human-animal hybrid stem cell techniques when developments in IPS [induced pluripotent stem] cells may allow similar work,” he told the BMJ. Induced pluripotent stem cells are produced by reprogramming adult human cells, such as skin cells, to become pluripotent (able to develop into a variety of cell types) by inserting DNA fragments into their genetic material.

Dr Minger agreed that distribution of research funding should be competitive, based on assessment of scientific value and cost, and noted that induced pluripotent stem cells are cheaper to set up than human-animal hybrid stem cell research.

His grant application included nearly £80 000 for new micromanipulation equipment.

Cite this as: BMJ 2009;338:b207
Doctor is released from custody: Mohammed Asha, the neurologist who was cleared of involvement in the London and Glasgow car bomb plots, has been granted bail pending his appeal against deportation to Jordan, his home country (BMJ 2009;338:a3170). Dr Asha, who was working for the University Hospital of North Staffordshire in Stoke-on-Trent when he was arrested in June 2007, has been in prison since he was acquitted in December 2008. His bail conditions mean he should be able to resume work.

French doctors found not guilty of manslaughter: Six doctors and pharmacists who were on trial in France over the death of 117 people who became infected with Creutzfeldt-Jakob disease in the 1980s (BMJ 2008;336:348-9) after being given tainted human growth hormone were acquitted on 14 January of all charges, including manslaughter and aggravated deception. The public prosecutor’s office has appealed against the acquittals of three of the accused.

Cochrane reviews are more likely to have negative findings: Non-Cochrane systematic reviews involving a meta-analysis of the primary outcome were twice as likely to have positive conclusions as Cochrane reviews with such an analysis (P0.05) (Journal of Clinical Epidemiology doi:10.1016/j.jclinepi.2008.08.008).

Measles vaccination in Germany must target older children: Measles won’t be eliminated in Europe by 2010 unless Germany has an immediate nationwide, school based, catch-up vaccination campaign targeting older children, says a report that was based on an investigation into an outbreak of 1749 cases that showed that the spread of cases had shifted to older age groups (BMJ 2008;337:1285). Vaccination campaigns in 2007 alone were estimated to have covered 40% of 5-6 year olds and 20% of 10-14 year olds (Clinical Epidemiology doi:10.1016/j.clinepi.2008.08.008).

The national organ body, Deutsches Organtransplantationsregister (DeO), says that the decline is partly because of the indifference of hospitals to transplantation—they are meant to register potential donors, but often fail to do so—and partly because of a change in the law on tissue donation in 2007, which said that hospitals and tissue banks have to fulfil stringent new criteria, similar to those governing the drug industry (BMJ 2006;333:774).

The organisation thinks that nothing will change until the government gives it more power. “By introducing appropriate measures the number of organ donations could be doubled,” says Günter Kirste, the organisation’s medical director.

He thinks that organ donation in Germany
US prisoners are much sicker than average Americans

Janice Hopkins Tanne NEW YORK

The first national study of the health of US prison inmates shows that they are much sicker than other Americans of the same age and have poor access to health care. Better health care for prisoners would benefit the community, because about 12 million inmates are released each year, thus bringing their health problems and infections into the community, the report says.

The authors of the study, carried out by the Cambridge Health Alliance and Harvard Medical School, write: “The prison population of the United States has quadrupled in the past 25 years and the country now incarcerates more people per capita than any other nation” (American Journal of Public Health doi:10.2105/AJPH.2008.144279).

About 750 per 100 000 US adults are in prison, about five times the proportion in the United Kingdom (148 per 100 000). Most inmates are male, aged younger than 35, disproportionately from black and Hispanic ethnic groups, and parents of small children.

About 750 000 of the nearly 2.3 million inmates say they have one or more chronic conditions, “but their access to care appears to be poor, particularly in jails [short term facilities rather than long term prisons],” the report says.

Access to medical care was worst in local jails and best in federal prisons. No medical attention was given to about 14% of inmates in federal prisons with a persistent medical condition, whereas the percentage was 20% among state prison inmates and 68% among local jail inmates. Between 26% and 40% of people taking a prescription drug when they entered the prison system did not receive the treatment after they entered the system.

The study looked at data from a 2002 study of inmates in local jails and a 2004 survey of inmates in state and federal prisons. Both studies were carried out by the US Census Bureau for the Bureau of Justice Statistics. Participation in the surveys was voluntary, and prisoners’ answers were anonymous and confidential. Of 16 152 randomly selected inmates, 14 499 completed interviews (a response rate of 90%).

The inmates were asked about their symptoms or diagnoses before incarceration, persistent health problems, serious injuries received since incarceration, and their health care while imprisoned.

The researchers compared the prisoners’ answers with those from a similar survey of a nationally representative sample of the non-institutionalised population from the 2003-4 US national health and nutrition examination survey.

When compared with other Americans of the same age, inmates in state prisons were 31% more likely to have asthma, 55% more likely to have diabetes, and 90% more likely to have had a heart attack, the study says.

Chronic medical conditions such as heart problems, hypertension, diabetes, kidney problems, asthma, cirrhosis, hepatitis, and HIV infection were common among prisoners. The prevalence of chronic medical problems ranged from about 38% to 42%.

“Mental health problems were ubiquitous,” the authors say; the prevalence ranged from about 15% to 25% of prisoners.

Cite this as: BMJ/2009;338:b208

more authority to increase donations

should be modelled on the Spanish system, which achieves a donation rate of 34 donors per million population, the highest in Europe. In Germany the donor rate in 2008 was 14.6 per million, says Professor Kirste.

He says that the German organ procurement association should have the right to identify donors in intensive care units, talk to relatives, and organise all the other necessary procedures of organ donation in the hospitals. “It is high time that the DSO was given the power to run organ donation in hospitals and no longer had to beg to be involved in hospitals,” he added.

He deplored the fact that the number of donated organs declined by 200 last year to just under 4000. About 1000 people die each year while waiting for an organ.

Recent polls have shown that about 80% of the German population support organ donation, but only 14% carry a donor card. Attempts to change the law from an opt-in system to an opt-out arrangement, whereby everyone is assumed to be willing to donate their organs unless they have specified otherwise, failed in 2007, after objections from the DSO and the German Medical Association, which both wanted other options pursued first (BMJ/2007;334:973).

Cite this as: BMJ/2009;338:b206