Florida judge says health reform act is unconstitutional

Janice Hopkins Tanne NEW YORK

The entire health reform act is unconstitutional, declared Judge Roger Vinson of the Federal District Court in Pensacola, Florida, on 31 January.

He ruled that the “individual mandate” requiring citizens to have health insurance was unconstitutional. And because the health reform act relied on the mandate to be effective, he declared the entire act unconstitutional.

He said he recognised problems in the US healthcare system but added that the health reform act exceeded constitutional bounds.

In his ruling he wrote, “I must conclude that the individual mandate and the remaining provisions are all inextricably bound together in purpose and must stand or fall as a single unit.” He said that the US Congress had never before required people to buy a product or service because they might need it in future. If so, he wrote, “Congress could do almost anything it wanted.”

He wrote, “It is difficult to imagine that a nation which began…as the result of opposition to a British mandate giving the East India Company a monopoly and imposing a nominal tax on all teas sold in America would have set out to create a government with the power to force people to buy tea in the first place. If Congress can penalize a passive individual for failing to engage in commerce, the enumeration of powers in the Constitution would have been in vain for it would be (quoting an earlier decision) ‘difficult to perceive any limitation on federal power.’”

His ruling came in the most important challenge to the law. The case was brought by Florida and 25 other states, the National Federation of Independent Businesses, many Republican legislators, and several individuals.

Previously a judge in Virginia had ruled that the individual mandate was unconstitutional but did not declare the entire act unconstitutional (BMJ 2010;341:c7222, 14 Dec).

Two other judges have ruled that the health reform act is constitutional. The Florida case will be appealed through regional courts known for their conservative rulings. The issue is likely to reach the Supreme Court within two years, about the time of the next presidential election in November 2012.

Cite this as: BMJ 2011;342:d704

MPs support NHS changes as health bill passes first hurdle

Adrian O’ Dowd LONDON

Large scale change to the NHS in England came a step closer this week as MPs passed the Health and Social Care Bill in its first debate stage on 31 January.

Planned changes that will see GP commissioning consortiums taking control of most of the NHS budget and the abolition of primary care trusts and strategic health authorities were the subject of an often angry six hour debate in the House of Commons. But the bill was comfortably passed after 321 MPs voted for it and 235 voted against in its second reading.

Unease at the proposed changes among the medical profession continues, however, as shown by a new survey of doctors published by the Royal College of General Practitioners. The results show that 61% of GPs disagree with the general direction of the reforms.

At the start of the parliamentary debate the health secretary for England, Andrew Lansley, said, “While the previous government increased funding for the National Health Service to the European average, it did not act similarly to increase its quality of care. We spent more. Others spent better.”

This had been proved, he said, by figures from the Office for National Statistics, which had said recently that productivity in hospital services had fallen every year for the past 10 years by around 1.4% a year.

“Previous changes have tinkered with one piece of the NHS or another when what was needed was comprehensive modernisation,” said Mr Lansley.

Margaret Hodge, the Labour MP for Barking, asked whether it was wise to distract NHS staff with an “unnecessary constitutional reform” when they were trying to improve productivity and make savings.

Mr Lansley replied, “At every step, clinical leadership will be right at the forefront. The shift in power away from politicians and bureaucrats will be dramatic. This legislation builds on what has gone before.”

Labour’s shadow health secretary, John Healey, disagreed strongly, saying, “Make no mistake, this is a revolution not an evolution. These reforms are like an iceberg with big, substantial ideological changes hidden from public sight. These changes will break up the NHS. They are driving free market political ideology into the heart of the NHS. This is why doctors are now saying that, as it stands, the government’s new bill spells the end of the NHS.”

Clinicians were being misled, he added, saying, “GPs are being told they will call the shots on deciding who provides care for their patients, but they are being set up by the government. They are likely to find their hands tied by Monitor, by the Office of Fair Trading, and by the courts enforcing competition law. They are likely to find their decisions challenged by private companies if they don’t accept any willing provider, especially if they offer to undercut on price.”

David Miliband, the Labour MP for South Shields, said, “These proposals represent a set of poison pills for the National Health Service.”

For all the latest information and comment on the changes to the NHS in England, visit the BMJ NHS reform microsite at bmj.com/nhsreforms.

Cite this as: BMJ 2011;342:d711
New appointment of evangelical Christian to drug advisory body sparks controversy

Clare Dyer BMJ

Nine new members have been appointed to the UK Advisory Council on the Misuse of Drugs after a spate of resignations sparked by a row over threats to their independence by the previous Labour government.

A raft of members of the council, an independent body that advises the Home Office on drug policy, resigned in protest after the then Labour home secretary, Alan Johnson, sacked its head, David Nutt, in November 2009 over comments he made in an academic lecture (BMJ 2009;339:b4563). In the lecture Professor Nutt said that tobacco and alcohol were more harmful than cannabis, ecstasy, and LSD.

But the appointment of one of the nine new members, the Manchester GP Hans-Christian Raabe, has sparked new controversy. Dr Raabe, who stood for the European parliament for the Christian Peoples Alliance in 2009, is medically coordinator of the Council for Health and Wholeness, a Christian organisation based within the Maranatha evangelical Christian group in Manchester.

Briefing papers from the council to MPs describe homosexual people as having a “destructive” lifestyle and being prone to addictions and linked to paedophilia.

In a blog in the Guardian newspaper Evan Harris, the former Liberal Democrat MP and director of the new Centre for Evidence-Based Policy, questioned Dr Raabe’s qualifications for serving on an expert committee on drugs (www.guardian.co.uk/commentisfree/belief/2011/jan/25/gp-drugs-advisory-council).

He wrote, “The problem is that the ACMD [Advisory Council on the Misuse of Drugs] is an expert committee where even those members with political (ie, policy) views have them framed in the context of their experience in the field, or their scholarship, not merely their opinions.”

Dr Raabe strongly opposes the policy of harm reduction subscribed to by most professionals in the field. In a rapid response posted on bmj.com last October he wrote, “The only way of stopping people from dying from drug-related deaths is to prevent drug use in the first place!” (www.bmj.com/content/341/bmj.c5492/fullreply#bmj_el_242838).

The appointment approved by the home secretary, Theresa May (left), was criticised by Evan Harris

The BBC’s home affairs editor, Mark Easton, wrote in a recent blog, “I understand that at least one member of the council is so incensed by the appointment that he is considering resigning. The Home Office, which prompted seven resignations when it sacked ACMD chair Professor David Nutt, might find itself facing yet more as it tries to replace those who have gone” (www.bbc.co.uk/blogs/thereporters/markeaston/2011/01/another_acmd_member_threatens.html).

Mr Easton quoted an unnamed member of the council as saying, “The council prides itself on basing its views on evidence. This man put his name to documents which include very questionable views . . . His appointment makes me extremely uncomfortable.”

Recommendations for the unpaid appointments were made by a board comprising representatives from the Home Office and the council itself, with an assessor from the Office of the Parliamentary Commissioner for Appointments. The appointments, including confirmation of the interim chairman Les Iversen as the new chairman, were approved by the home secretary, Theresa May. They were made under a code of practice that requires all appointments to be made on merit.

A list of the new appointees is at www.homeoffice.gov.uk/media-centre/press-releases/acmd-members.

Cite this as: BMJ 2011;342:d624

Experts say drinks industry is not interested in health

Adrian O’Dowd LONDON

Collaborative working on public health issues between government, industry, and health experts is not producing concrete benefits, peers have been told.

Health experts involved in the government’s efforts to work collaboratively with the food and drinks industry as part of efforts to improve public health said the companies involved were unwilling to look at steps that would “hurt their bottom line” in business.

The lack of progress was discussed at an evidence session of the House of Lords science and technology select committee on 26 January as part of its inquiry into the use of behaviour change interventions to achieve government policy goals.

Lord Krebs, a crossbencher peer and committee member, said he was sceptical about the public health “responsibility deal” networks created by the Department of Health last year as a joint effort between businesses, public interest health and consumer groups, charities, the Faculty of Public Health, and ministers to come up with proposals and ideas for future government policies on diet and health problems.

“There are some elements of scepticism in our committee about the process of working with industry to achieve public health benefits where that might cut across the industry’s primary responsibility of maximising shareholder value and profit,” said Lord Krebs.

Vivienne Nathanson, head of science and ethics at the BMA and who sits on the alcohol network, giving evidence, said the networks were trying to work on these issues, but she had serious concerns.

“The industry, which is at least two thirds of the membership of the group, is not motivated so far to really look for things that hurt them,” said Professor Nathanson. “They are looking at completely protecting their bottom line, which I can understand—they are businesses. “But from the health side, we want to hurt their bottom line. We want to see that alcohol harm can be significantly reduced. The health groups are working together to try to, but we have some serious concerns about whether it’s possible given the background interests of the industry.”

Fellow witness Susan Jebb, head of nutrition and research at the Medical Research Council and chair of the cross government expert advisory group on obesity and the “responsibility deal” food network, also told peers of her concerns.

“What’s vital for me is that the goals are set by public health bodies and that business is charged with helping to shape the delivery of those goals but not in setting the goals,” said Dr Jebb.
BMA calls special meeting to discuss NHS reforms concerns

Zosia Kmietowicz LONDON

The BMA has called a special representative meeting to debate the NHS reforms in England.

The BMA council said it was appropriate to discuss the planned changes to the NHS now that the Health and Social Care Bill has been laid before parliament. The meeting will take place on 15 March. Representatives were last called to a special meeting in 1992 when John Major’s government was attempting to introduce NHS reforms to separate purchasers from providers (BMJ 1992;304:920-21).

The council sets out its concerns over the reforms in a briefing published on 26 January. It calls for several amendments to the bill and says that the government should halt all further implementation of the reforms while the legislation makes its way through parliament.

In particular the BMA says it is concerned about the enforcement of competition through Monitor’s new role as the economic regulator of the NHS and the “inappropriate” introduction of price competition between providers.

“Commissioning consortia should be able to place contracts with the most suitable providers without fear of being accused of anti-competitive behaviour,” says the briefing. “They should be free to design new clinical pathways built around integration of services, inclusivity and partnership.”

The risk is that price competition will “damage the ability of the NHS to provide services in the most efficient and cost-effective way. It will destabilise provision, and increase transaction costs, and will threaten the provision of essential local services.”

The BMA is also opposed to the idea that all NHS trusts should be forced to become foundation trusts by 1 April 2014—a move that it says “could distort priorities and drive trusts to place the achievement of this target above all others, including safe patient care.”

On the same day the prime minister, David Cameron, issued a rallying cry to the medical profession in the form of a letter to the 182 000 members of doctors.net.uk in which he reiterated why the reforms were necessary and the benefits they were designed to deliver.

Mr Cameron repeated many of the messages he made during his address at the Royal Society of Arts on 17 January, two days before the bill was published (BMJ 2011;342:d363), when he said that poorer outcomes in England than in the rest of Europe meant the status quo could not continue.

He ends his letter with, “Our plans for modernisation will create an NHS that is more open, more local and more personal. They’ll free you to deliver first-class, world-class, services. And they’ll help make our National Health Service the envy of the world. That’s a rich prize—so together, let’s make it happen.”

The BMA’s second reading briefing is at www.bma.org.uk/healthcare_policy/nhs_white_paper/healthsocbillsecondreading.jsp.

Cite this as: BMJ 2011;342:d594

US manufacturer of lethal injection stops drug production

Clare Dyer BMJ

The only US manufacturer of thioental sodium, the anaesthetic widely used in the execution of death row prisoners in the US, has decided to pull out of the market amid European opposition to the death penalty.

Hospira, which ceased manufacture of the drug in the US, had been about to move production to its factory in Italy. But the Italian government said it would permit the company to make the drug there only if it could guarantee that it would not be used for lethal injections.

Hospira claimed that conversations with wholesalers “led us to believe we could not prevent the drug from being diverted to depart- ments of corrections for use in capital punish- ment procedures.”

The company said it could not take the risk that it would be held liable by the Italian authorities if the product was diverted for use in capital punishment.

The unavailability of the drug in the US has delayed executions and driven prison authorities to import it from other countries, especially the UK. The UK business secretary, Vince Cable, imposed import restrictions on it last November, but the charity Reprieve, which campaigns against the death penalty, claims that enough supplies had been sent to the US from the UK to kill 90 inmates.

Under a three drug protocol, thioental sodium anaesthetises the prisoner, pancuronium bromide paralyses him, before potassium chloride is administered to cause a fatal heart attack. Mr Cable is considering imposing restrictions on the export of the other two drugs.

Emmanuel Hammond, a prisoner on death row in Georgia, was executed on 25 January with thioental sodium supplied by Dream Pharma, a small wholesaler operating out of a driving school in west London, according to documents obtained by Reprieve.

Cite this as: BMJ 2011;342:d590

Peers asked about voluntary agreements and whether they worked because of a conflict of interests for industry.

Professor Nathanson replied: “The health members of the alcohol network believe that inherently voluntary agreements won’t work. Those voluntary agreements have got to have real teeth, and we have very real doubts that they ever will have.”

Earlier in the session Paul Kelly, external affairs director for the supermarket chain Asda, also gave evidence and said he believed industry voluntary agreements were the way forward.

Cite this as: BMJ 2011;342:d591

Paul Kelly, an Asda executive, said voluntary agreements with industry were the way forward
IN BRIEF

MPs are to hold inquiry into peer review: The UK House of Commons Science and Technology Committee is inviting submissions on all aspects of the operation and effectiveness of the peer review process for examining and validating scientific results and papers before publication. Submissions should be no longer than 3000 words and sent to scitechcom@parliament.uk by Thursday 10 March. A Public Bill Committee on the Health and Social Care Bill is also asking for evidence.

Six doctors are accused over prison death: Six doctors have been ordered to stand trial by a judge in Rome in connection with the death of a man in an Italian prison hospital. Stefano Cucchi, 31, died in October 2009 after being assaulted by police, prosecutors allege. They say that doctors failed to carry out even “the most basic checks” on the injured man.

GSK settles with litigant over rosiglitazone: GlaxoSmithKline has agreed to settle a US lawsuit over its disputed antidiabetes drug rosiglitazone (Avandia) on the eve of the case going to court. The company said that it had resolved the suit brought in Philadelphia by the family of rosiglitazone user James Burford, who died in 2006. GSK declined to give details of the settlement. The drug has faced difficulties since a 2007 study claimed an association with an increased risk of heart attacks (New England Journal of Medicine 2007;356:2457-71, doi:10.1056/NEJMoa072761).

Death of AIDS activist is condemned: Last week’s murder of the Ugandan gay rights activist David Kato has brought international condemnation. Mr Kato was bludgeoned to death after being depicted in a newspaper article exposing alleged homosexuals, with the caption “Hang them.” He had successfully campaigned against proposed legislation which provides for complete a survey about their HIV status, despite a recent law that provides for stopping treatment is “cruel to give personal data violates their human rights, and stopping treatment is “cruel and dangerous,” said Andriy Klepikov, director of the International HIV/AIDS Alliance in Ukraine.

Ukraine withholds treatment of injecting drug users: Legal opioid substitutes are being denied to drug dependent patients in Ukraine until they complete a survey about their HIV status, despite a recent law that provides for substitution therapy. Forcing drug users to give personal data violates their human rights, and stopping treatment is “cruel and dangerous,” said Andriy Klepikov, director of the International HIV/AIDS Alliance in Ukraine.

US health department recovers $4bn through antifraud action

Janice Hopkins Tanne NEW YORK

The US Department of Health and Human Services and the Department of Justice announced on Monday 24 January that the government’s healthcare fraud prevention and enforcement efforts had recovered more than $4bn (£2.5bn; €2.9bn) in the 2010 fiscal year. The money came from drug companies, hospitals, doctors’ offices, nursing homes, and other healthcare providers that had cheated the government. It was “the highest annual amount ever recovered from people who tried to defraud seniors and tax payers,” the departments said in a joint statement.

The $4bn had been stolen from federal healthcare programmes and was returned to Medicare, which provides health insurance for elderly people, the Treasury, and other programmes.

The secretary of health and human services, Kathleen Sebelius, and associate attorney general, Thomas Perelli, announced the new report. They said that President Barack Obama had made fraud detection and especially prevention of fraud a top priority from the beginning of his administration.

At the same time Ms Sebelius announced new tools to improve the government’s efforts to detect and punish fraud against Medicare, Medicaid (which provides health insurance for poor people), and the Children’s Health Insurance Program.

The tools, authorised by the health reform act passed last March, create a rigorous screening process for providers and suppliers enrolling in government health insurance programmes. The rules went into effect on 24 January.

Ms Sebelius and Mr Perelli credited joint efforts by their departments to coordinate federal, state, and local law enforcement activities to fight healthcare fraud and abuse.

The departments have organised summit meetings around the country and contacted state attorneys general, urging them to work with the federal health department and federal, state, and local law enforcement officials. They have encouraged law enforcement officials to set up outreach campaigns to educate people who are insured by Medicare on how to prevent Medicare scams and fraud.

Last year the departments increased to seven the number of cities or boroughs with prosecution teams dedicated to fighting fraud: Miami, Los Angeles, Detroit, Houston, Brooklyn (New York), Baton Rouge (Louisiana), and Tampa (Florida). The teams use advanced data analysis techniques to spot new and continuing fraud schemes. In South Florida, which includes Miami and has many elderly residents, several investigations focused on providers of durable medical equipment, such as wheelchairs, that were charged to Medicare but were not necessary or were never provided.


Cite this as: BMJ 2011;342:d615

Older Americans are paying the price of high smoking rates in the 1950s and 1960s

Bob Roehr WASHINGTON, DC

High levels of cigarette smoking in the past and rising rates of obesity are the primary reasons why US citizens older than 50 do not live as long as citizens in other industrialised nations. The study by the National Research Council, part of the National Academy of Sciences, was released on 25 January. Although life expectancy has risen in the US over the last 25 years, it had done so at a slower pace than in most other high income countries, despite the fact that the US spends far more on healthcare per person than any other nation.

“Fifty years ago, smoking was much more widespread in the United States than in Europe or Japan: a greater proportion of Americans smoked and smoked more intensively than was the case in other countries. The health consequences of this behavior are still playing out in today’s mortality rates,” said the report.
MEPs criticise WHO for alarm created by H1N1 pandemic advice

Rory Watson BRUSSELS

The European parliament has launched a strong attack on the World Health Organization, accusing it of distorting the term “pandemic” during the H1N1 outbreak in 2009-10 and triggering a worldwide false alarm. That, in turn, gave rise to inappropriate and disproportionate public health decisions by European Union countries, members of the parliament claim.

The criticism comes in a report drafted by the French Green MEP Michèle Rivasi evaluating management of H1N1 flu in 2009-10 in the European Union. The report was overwhelmingly adopted by the parliament’s public health committee on 25 January, with 58 votes in favour of the report, just two against, and one abstention.

It calls on WHO to revise the definition of a pandemic to take account not just of the geographical spread of a health threat but also its severity.

Quoting figures from the Stockholm based European Centre for Disease Prevention and Control, Mrs Rivasi pointed out that H1N1 flu caused 2900 deaths in Europe in 2009. In contrast, seasonal flu kills some 40 000 people in a moderate year and 220 000 in a particularly severe season. Yet governments invested heavily in preparing for the pandemic. The costs were put at €1.3bn (£1.1bn; $1.8bn) for the United Kingdom and €990m for France.

The parliamentary report also deals with the issue of potential conflicts of interest—the focus of an earlier investigation by the Council of Europe into the events surrounding the H1N1 outbreak (BMJ 2010;340:c3033). MEPs have requested that a common definition of what constitutes a conflict of interest be adopted.

Cite this as: BMJ 2011;342:d574

Spain’s tough line on smoking in public spreads to other countries

Aser García Rada MADRID

The new Spanish law on smoking in public places, which came into force on 2 January (BMJ 2010;341:c7429), is already having an effect on other countries’ laws, the World Health Organization has said.

Armando Peruga, programme manager of WHO’s Tobacco Free Initiative, said, “Sending the message that it [a soft approach to smoking in public places] doesn’t work is a severe blow for the tobacco industry. The health minister of Chile has announced that they will follow the new Spanish model.”

Mr Peruga was speaking at a meeting in Madrid organised by the Spanish National Association of Health Journalists and the National Committee to Prevent Smoking on 25 January.

The new law in January brought to an end the “Spanish model” of permissive smoking legislation. In force since 2006, the previous law had numerous loopholes and meant that 90% of bars and restaurants continued to allow smoking, so that smoking was viewed by most as socially acceptable. The new law bans smoking in all indoor public places and also children’s playgrounds and areas outside hospitals and schools.

Mr Peruga said that other countries were planning to implement similarly tough legislation. The Greek government, which has been considering weakening its current law on smoking in public places, has also decided to keep strong restrictions in force after the passing of the law in Spain, he said.

The Spanish decision has had a “very important dynamic effect,” Mr Peruga told doctors and journalists. However, he warned that the “first lesson is that work has just begun,” and he encouraged the audience to “fight against the interests that will try to roll back this law.”

The tobacco industry in Spain has lobbied hard to prevent the introduction of tougher rules on smoking (BMJ 2010;341:c6662, 15 Nov), he said, and would continue to do so.

Cite this as: BMJ 2011;342:d617

“Obesity also appears to be a contributor; the US is the heaviest country in the western world,” said Professor Preston. “It is contributing a fifth to a third of this shortfall in life expectancy.” English speaking countries are generally heavier than non-English speaking ones, he added.

Cite this as: BMJ 2011;342:d574
Gates and Cameron pledge new money to eradicate polio

John Zarocostas DAVOS, SWITZERLAND

The philanthropist Bill Gates and the UK prime minister, David Cameron, have pledged additional funding to the global polio eradication initiative and have called on other donors to step up with new commitments.

Mr Gates said that his foundation was adding $100m (£62m; €73m) today to the polio campaign to help close the gaps. "He said there was a need to intensify the campaign; it will cost almost $1bn to buy the polio vaccine drops needed for eradication over the next two years.

Mr Cameron said that the United Kingdom would be doubling its support to the initiative over the next two years, from £20m to £40m. "This will enable the vaccination of an extra 45 million children," Mr Cameron told business and political leaders at the annual World Economic Forum in Davos, Switzerland, on 28 January. But he also wanted to impose two conditions. Firstly, vaccination must become routine in countries where polio has become endemic; and, secondly, support needs to be leveraged so that for every $5 pledged by others the UK will increase its support by $1 up to the $60m (£40m) covering 2011 and 2012.

Bruce Aylward, director of the global polio eradication initiative at the World Health Organization, told the BMJ, "The contribution by Britain is brilliant and a real challenge to other G8 and G20 countries."

Dr Aylward said that the contribution will help to narrow the funding gap—estimated at $720m for 2011 and 2012.

Mr Cameron said it was essential to put extra money towards finishing the job. If eradication does not happen, he cautioned, polio could rise again and spread to other countries.

"We know we can do it. We did it with smallpox; we know we can do it with polio. I think we need to go this extra mile and put the extra money in to make sure it can be done," he said.

Margaret Chan, director general of WHO, said, "We have a window of opportunity now, with cases at an all time low... Only eradication will ensure that polio does not re-emerge as a global threat."

WHO estimates that the annual incidence of polio has fallen by more than 99% since 1988, from an estimated 350000 cases to 946 reported cases in 2010.

In countries where polio is endemic—Afghanistan, India, Nigeria, and Pakistan—the picture is mixed. In India the number of cases fell sharply to 42 in 2010 from 741 in 2009, and in Nigeria it fell to 20 from 388. But in Pakistan the number of children paralysed by polio rose by 60%, from 89 in 2009 to 144 in 2010.

Imported cases were also reported by 16 non-endemic nations, with the Democratic Republic of Congo and Tajikistan experiencing the largest numbers: 93 and 458 cases, respectively.

Mr Cameron said that in spending money on fighting preventable diseases it was important to have the backing of the public, but he added that vaccination "is one of the easiest things to sell to a sceptical public."

Mr Cameron added, "You don’t have any [economic] development if people are dying of preventable diseases." It has to be, he said, "our first line in all our development policies."

Cite this as: BMJ 2011;342:d660

US firms may have to prove safety of ECT machines

Janice Hopkins Tanne NEW YORK

A committee of the US Food and Drug Administration has recommended that devices used to deliver electroconvulsive therapy (ECT) should remain classified as class III devices, the highest risk category.

The ruling may require the two companies that make the devices in the United States to conduct trials to demonstrate the safety and effectiveness of the devices for the first time. The companies say that the cost of such studies may be prohibitive.

The recommendation from the FDA’s neurological devices advisory committee was made on 28 January. The FDA usually, but
Widening the market for drugs affects safety, report says

Janice Hopkins Tanne NEW YORK

Drug companies show a clear, repeated pattern in which “drugs discovered with good science for a specific set of patients are marketed to a larger population” for whom they are less appropriate and less safe, says Howard Brody, professor and director of the Institute for the Medical Humanities at the University of Texas Medical Branch in Galveston.

The “inverse benefit law” was published online in the American Journal of Public Health (doi:10.2105/AJPH.2010.199844).

Dr Brody told the BMJ, “You have to be really sceptical and careful not be seduced by research findings that are apparently very valid scientifically, but if you drill down they are really industry marketing disguised as research rather than scientifically valid research.”

The inverse benefit law echoes Julian Tudor Hart’s “inverse care law,” which says that availability of good medical care varies inversely with the need for it in the population (Lancet 1971;1:405-12).

The inverse benefit law says that patients with the most severe symptoms or the highest level of risk will receive the greatest benefit from treatment with a drug. The risk of an adverse event, however, is spread among all people receiving the drug.

Because only a few people would receive the drug on the basis of evidence based treatment, marketing from drug companies seeks to increase the number of people who should be treated, using six mechanisms:

• Reducing the threshold for diagnosing disease, such as lowering the level for diagnosing type 2 diabetes and hypertension

not always, follows its advisory committees’ recommendations.

By regulating ECT devices the FDA is in effect regulating the use of ECT treatment. The main indications for such treatment are unipolar and bipolar depression, schizophrenia, bipolar manic (and mixed) states, catatonia, and schizoaffective disorders. An estimated 100 000 people receive the treatment each year in the US, about two thirds of whom are women. (Depression is more common among women.)

The most serious problems reported with treatment are memory dysfunction, cognitive dysfunction, brain damage (neuropathological changes), and death. The panel also received complaints of improper consent to treatment, ineffectiveness of treatment, and device malfunctions.

In 2009 the federal Government Accountability Office recommended that the FDA review the ECT devices, which have been on the market since the 1930s. They were included as class III devices when the FDA was given more power to regulate certain medical devices in 1976. Such devices now require pre-market approval, but these (and some other) devices were included because they were already in use and were thought to be safe and effective.

The accountability office said that the FDA should either downgrade the devices to class I or II devices, indicating that they are of lower risk, or request the trials to demonstrate their safety and effectiveness. The FDA conducted an independent review, including meta-analyses, of their safety and effectiveness and elicited comments from the public and device manufacturers. After a two day session the FDA concluded that the devices should remain in class III, but opinion was divided on whether they should be downgraded to class II when used in catatonia.

The American Psychiatric Association said it was “pleased that patients will continue to have access to lifesaving electroconvulsive therapy.” Its president, Carol Bernstein, said, “ECT is appropriate for a small percentage of patients, generally those with severe mental illnesses that have not responded to other treatments. When used properly, under the appropriate guidelines and by a well trained psychiatrist, ECT is extremely safe and effective.”

Cite this as: BMJ 2011;342:d598

Companies say that the cost of running studies to prove the safety and effectiveness of ECT devices could be prohibitive

Relying on surrogate end points, such as glucose concentrations and blood pressure levels, rather than patient outcomes such as myocardial infarction, stroke, and death

Exaggerating safety claims (so that doctors prescribed newer antipsychotics more often, for example)

Exaggerating effectiveness claims—as with cyclo-oxygenase-2 inhibitors, which were later shown to be no better as analgesics than older non-steroidal anti-inflammatory drugs, had only a modestly lower risk of gastrointestinal bleeding, and were later found to raise cardiovascular risks

Creating new diseases, such as social phobia, pre-diabetes, and pre-hypertension; and

Encouraging unapproved uses—through continuing education campaigns, talks by physicians, and ghostwritten articles. To counter the “inverse benefit,” Dr Brody and his coauthor, Donald Light of the University of Medicine and Dentistry of New Jersey, suggest that writing treatment guidelines should be restricted to groups free of commercial interest. A neutral agency such as a branch of the National Institutes of Health or the Agency for Healthcare Research and Quality should conduct drug trials and comparative effectiveness research.

Creation of “new diseases” could be lessened by restricting drug companies’ input in clinical guidelines. Marketing by drug company sales people would be reduced if most US doctors refused to meet them—but now 94% of US doctors do so.

Cite this as: BMJ 2011;342:d661