"Heart disease is the #1 health problem in America. Stroke is #3. Lipitor helps reduce the risk of both."

DR. ROBERT JOHNSON — *Member of the Texas Medical Board*

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Lipitor lowers bad cholesterol.**

*Lipitor is not a substitute for a healthy diet and exercise program.

Unlike some cholesterol-lowering medications, Lipitor has been approved to reduce the risk of heart attack and stroke in those who have several common risk factors for heart disease. Risk factors include family history, high blood pressure, age, low HDL ("good") cholesterol or smoking.

IMPORTANT INFORMATION: LIPITOR is a prescription drug. It is used in patients with multiple risk factors for heart disease such as family history, high blood pressure, age, low HDL ("good") cholesterol or smoking to reduce the risk of heart attack and stroke. When diet and exercise alone are not enough, Lipitor can be used along with a low-fat diet and exercise to lower cholesterol.

Call your doctor about all of the medicines you take. This may help avoid serious drug interactions. Your doctor should be made aware of how your heart function before, during treatment and may adjust your dose. The most common side effects are gas, constipation, muscle pain and headache. There may be to mild and often go away.

Please see additional important information on next page.

LIPITOR is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, pregnant or may become pregnant. If you take LIPITOR, tell your doctor about all the medicines you take. Lipitor may cause muscle pain or weakness. This could be a sign of rare but serious muscle side effects.

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Sweetening the pill

Can big pharma be trusted to provide independent health information to patients?
Hannah Brown investigates

When, in 2002, the European parliament voted resoundingly against allowing drug companies to provide information about their products directly to patients, public health lobby groups thought that the matter had been firmly dismissed. However, five years on, the resurgence of intense discussions about the “liberalisation of patient information,” as the European Commission refers to it, suggests that parliament’s resolve is set to be challenged again.

At issue is a set of proposals for relaxing the current laws that limit drug companies' communication with patients to the fixed format safety summary contained inside drug packaging. For the commission, which drafts European Union legislation, this debate is a trade-off between nurturing the competitiveness of one of the EU's biggest industries and respecting the concerns of public health organisations. What worries campaign groups most is that the commission seems to be ignoring them.

Hard lobbying by the drug industry has

convinced the EU enterprise and health commissioners that increasing the extent to which drug companies can provide information to patients is essential to stop Europe's drug industry falling further behind those of the United States and Japan. The rationale seems to be that giving patients more information would increase the demand for treatment. Drug companies also assert that this change would benefit patients. US residents, they argue, have their information needs met by reams of reliable reference material financed by the industry's huge resources. Patients in the EU, by contrast, must rely on the hotchpotch of potentially flawed internet sites. However, health campaign groups insist that drug companies cannot provide the independent information consumers need. And research published last month suggesting that UK consumers are put off by medical information sites that contain a lot of advertising (because they perceive a connection between advertising and biased material) suggests that patients may also dispute the industry's logic.

The commission will set out its final posi-

tion in a report expected to be released next month. But speculation is already rife that this document is likely to recycle the unpopular suggestions dismissed by the European parliament in 2002 and suggest changes to legislation that would jeopardise the current ban on direct to consumer advertising for prescription drugs.

Competitiveness

Years of bitter wrangling between health campaigners, drug companies, and their respective supporters in both the commission and parliament, have led up to this point. The discussions began in earnest in 2001 when, concerned that the EU's drug industry had dropped behind its US and Japanese counterparts in innovation and profits, the commission set out to find ways to boost the industry's competitiveness. From the start, balancing economic and health priorities was a key objective. However, the first attempt to provide a forum for negotiating these diverse interests seemed to pay only lip service to the notion of balance.

The commission set up a discussion forum

This debate is a trade-off between nurturing the competitiveness of one of the EU's biggest industries and respecting the concerns of public health organisations

called G10 Medicines in March 2001, comprising the health and enterprise commissioners, industry ministers from five member states, representatives from different sectors of the industry and mutual health funds, and a specialist in patient issues. Membership was kept intentionally small to make a consensus easier to achieve.

The group came up with a set of proposals on which they all agreed in just 12 months. And, as expected, the recommendations for enhancing industry competitiveness included a relaxation of restrictions on drug companies communicating directly with the public, as well as suggestions for modifying the way drug prices are set and methods for assessing the cost effectiveness of medications.

Around the same time, the European parliament was debating a set of amendments to existing patient information laws, introduced as part of a wide ranging revision of EU drug legislation. The commission, which came up with the changes after participating in the G10 discussions, had proposed that industry produced information for patients should be allowed for three diseases—HIV and AIDS, asthma, and diabetes—with the proviso that any material must conform to an industry authored code. Parliament's reaction was unequivocal: 70% of members of the European parliament (MEPs) voted against the proposed change.

Despite this vociferous reaction from MEPs, the commission made no attempt to disguise its disappointment with the outcome. Erkki Liikanen, the enterprise commissioner at the time, went so far as to suggest that parliament had endangered health by rejecting the amendments because, he said, patients would be forced to seek information about drugs from US websites that might not be applicable to medicines sold in the EU.

Even after the unpopular G10 group formally came to an end in June 2004, the commission did not lessen its resolve to advance the discussion over patient information. It set up a larger and more inclusive successor to the G10, called the pharmaceutical forum, to come up with practical ways to take liberalisation of patient information forward and increase the competitiveness of the industry.

Earlier this month, the patient information working group of the pharmaceutical forum finally published a consultation on its tenta-

tive conclusions, including a pilot information package on diabetes and a set of "quality principles" to govern production of future information material for patients.

Advertising by default

Campaigners who objected to the working group preliminary proposals during the pharmaceutical forum's most recent meeting in September last year have serious concerns about the proposals, however. They claim that the lack of a mechanism to ensure that quality criteria are adhered to means that if the commission decides it needs to relax the laws governing the way drug companies communicate with the public then direct to consumer advertising would be introduced almost as a side effect. But according to German MEP Jorgo Chatzimarkakis, one of the three MEPs on the pharmaceutical forum, blatant advertising is not the intention of anyone in the forum. "The advertising of medicines is not an objective. The working groups and the pharmaceutical forum are in agreement on this point and it is not debatable," he told the magazine *Europolitics* in an interview last month.

Mr Chatzimarkakis believes the EU has a real dearth of information and that industry sourced information is the right way to solve it. However, Barbara Mintzes, of the Center for Health Services and Policy Research, University of British Columbia, who is a keen observer of the debate over patient information, disagrees. She says that because of the difficulties of coming up with a definition of information that excludes everything that looks like promotional material, any change in the law to allow industry to provide information could produce undesirable effects—even if the advertising ban remains in place.

Ms Mintzes says the experience in her country shows how difficult a situation it can be. Canada main-

tains a ban on direct to consumer advertising but has started to allow “help-seeking” and “reminder” advertisements which, respectively, alert consumers to unspecified new products for various diseases or display the name of a product without revealing its use. For instance, she explains, if advertising is defined as anything about a product or disease that includes the name of the manufacturing company, the law would mean that drug companies could run disease awareness campaigns that did not mention the industry funding.

“Certainly in Canada we have seen these kinds of campaigns,” she says. “For [Pfizer’s proprietary statin] Lipitor, for example, there were advertisements that didn’t mention the drug or the company but just showed the tagged toe of a corpse and urged people to go and get their cholesterol tested,” she explains.

Ms Mintzes also takes issue with Mr Chatzimarkakis's conviction that industry can solve the perceived lack of appropriate patient information. "There is no discussion of whether industry is going to be an unbiased source about its own or other products or decisions not to treat," she says.

Rita Kessler a project manager for the campaign group AIM (the international association of mutual health funds), which represents social health insurance organisations in 17 EU states and is part of the

pharmaceutical forum, agrees. She says the current proposals, which were discussed in September, would result in poor quality information. "They the pharmaceutical forum make no proposal on the assessment of this information and they don't say who would be responsible for quality control. Practically, this would mean that no one would be responsible," she says.

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She questions whether it is appropriate for the European Commission to try to encourage anyone, let alone drug companies, to produce more health information. "There are already a lot of bodies that are producing independent reliable information. It is better to help patients to identify this information rather than add new information." Her organisation suggested at the pharmaceutical forum's September meeting that the commission should instead endorse an EU logo mark that would be awarded to high quality information sources and act as a trust certificate or quality stamp to help patients identify reliable, evidence based advice.

AIM's position is that drug companies should respect that their involvement with information provision should extend to the package information and nothing else. "Our message is be careful and don't make the confusion between public health interests and commercial interests," Mrs Kessler explains.

In anticipation of the commission's final report in April, five international health associations have joined forces to step up their opposition campaign. In a declaration outlining what they believe to be fundamental principles for the provision of reliable health information, they assert that "relevant, comparative and appropriate information on health issues cannot be provided by drug companies," because in a competitive marketplace, drug companies must present their own products in a more favourable light than other preventive or therapeutic options.

But, says Mrs Kessler, it is difficult to predict whether this opposition will sway MEPs when the proposals are debated in parliament. "It is a strong industry and they will battle very hard to maintain their advantages," she says. The fact that European parliament elections are coming up soon could have some bearing. "Health topics are very sensitive and people who want to be elected would like to be seen well, so there will be a lot of argument," Mrs Kessler predicts.

The quick turnaround of MEPs means that few of the original objectors from 2002 remain in office—and that could mean a completely different outcome when patient information laws are debated again. Asked last month what underlay his optimism in pushing through patient information changes, Mr Chatzimarkakis replied simply: "Now, 75% of the members of parliament are new."

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What makes an expert?

Autism activists are behind a journal's decision to retract a paper claiming a preservative once routinely used in vaccines is responsible for the condition.

Brian Deer examines the facts

Last October, *Autoimmunity Reviews* published online the draft of a seven page paper by reporting laboratory and clinical tests suggesting that thiomersal, a mercury based preservative once routinely added to most vaccines, was the main culprit for a sharp rise in diagnoses of behavioural disorders.¹ The paper was written by Dr Mark Geier, a self employed American geneticist, and his son David. The pair also reported treating autistic children with a hormone product, leuporelin acetate, which is sometimes prescribed for precocious puberty. They claimed that the drug produced "very significant overall clinical improvements" with "minimal" adverse effects.¹

But even before the journal posted its finalised contents page, Kathleen Seidel, an autism activist in Peterborough, New Hampshire, who runs the website neurodiversity.com, criticised the paper in a 2500 word email sent to the journal's editors-in-chief, Yehuda Schoenfeld of Tel Aviv University, and Eric Gershwin of the University of California, Davis, and copied to all 42 members of the journal's editorial board.²

One of Ms Seidel's complaints concerned

the Geiers' apparent institutional review: "The seven-member IRB institutional review board consists of Mark and David Geier; Dr Geier's wife; two of Dr Geier's business associates; and two mothers of autistic children, one of whom has publicly acknowledged that her son is a patient/subject of Dr Geier, and the other of whom is plaintiff in three pending vaccine injury claims."

According to Ms Seidel, neither editor responded to her email, despite several approaches to them. US Federal Court records show that Drs Schoenfeld and Gershwin have both been retained as experts for claimants in vaccine litigation.

The Geiers' paper in *Autoimmunity Review* has now been retracted, but I have been unable to discover the journal's reasons for retraction and the editors have not responded to my emails and phone calls.

Professor Graham Hughes, formerly of the Rayne Institute at London's St Thomas's Hospital, and a member of the journal's board, was also unable to help. "All I know is that I got a rather heated 20-page email from a lady," he said when asked for his comments on the retraction. "I really don't know what it's about."