Warning signs

Giving drug firms immunity from prosecution over inaccurate labelling would not serve the public.

In April 2000, at a Vermont health centre, Diana Levine was injected with the anti-nausea drug Phenergan in what was supposed to be a vein, but was in fact an artery. The drug caused arterial spasms, which led to gangrene; in the end, Levine's hand and forearm were amputated. Arterial spasming was a known danger with this drug, which was labelled with a warning approved by the US Food and Drug Administration (FDA). Nonetheless, Levine sued Wyeth, Phenergan's maker, in Vermont state court, alleging that the labelling was inadequate. The jury agreed, and the court awarded Levine $6.8 million in damages. Wyeth has now appealed the verdict all the way to the US Supreme Court, which recently agreed to hear the case in October.

The question before the court is whether the FDA's seal of approval on a drug's label should preempt a plaintiff's right to sue the maker on the basis of labelling inadequacies. Such 'failure to warn' claims underpin the vast majority of drug-injury lawsuits. The drug companies maintain that the assessment of FDA experts, who carefully weigh the risks and benefits of a drug before approving its label, should trump the findings of inexpert juries confronted with grievously injured plaintiffs.

The companies have a point. Frivolous or misguided litigation can doom drugs that might have benefited millions. The cost of bringing a new drug to market averages as much as $1.7 billion by one estimate, not least because the companies have to meet a multiplicity of FDA requirements along the way. Fairness suggests that clearing all those hurdles should earn them at least some degree of legal protection — as long as they have shown due diligence in testing their drugs, and have openly declared all the relevant data, both pro and con. Nonetheless, 'some degree' is different from blanket immunity, which the court should avoid for at least two reasons.

First, the industry's argument wrongly implies that science can identify all the risks in advance with absolute certainty. FDA drug approvals are based on clinical trials that are necessarily limited in size and duration, so harmful side effects sometimes won't emerge until a drug is in broader use. Witness the painkiller Vioxx, which was taken by tens of millions of people before it was found to increase their risk of heart attacks and strokes. Removing the right to sue when new side effects emerge would rob most of those affected in the future of redress for their injuries.

Second, the industry's argument presumes that the FDA is poised to update warning labels at a moment's notice. As former FDA commissioner David Kessler said recently, this notion is "unrealistic". With 11,000 drugs on the US market, and nearly 100 more approved each year, the agency is overwhelmed trying to keep up with new side effects — making lawsuits in state courts an important complement to its regulatory efforts. And, as Kessler also noted, the threat of potential litigation helps to ensure that drug firms are prompt in reporting new adverse effects to the agency and working to update labels.

Supreme Court decisions are notoriously difficult to predict. But it is worth noting that in a recent decision that affects the most advanced, expensive and — in some cases — risky FDA-approved medical devices, the court granted manufacturers exactly the kind of immunity the drug industry is seeking in *Wyeth* v. *Levine*. To extend such broad-ranging protection to drugs would be both ill-advised and unjust. Whatever the justices decide, they must preserve the right of future Diana Levines to have their day in court. ■

The EIT farce

Universities should target the challenges that a virtual technology powerhouse probably won't meet.

When the European Parliament approved the controversial European Institute of Innovation and Technology on 11 March, one dissenting parliamentarian complained that the "initiative has degenerated into a farce". He judged it "poorly defined and under-funded". He was right.

The original 2005 concept was to recreate the Massachusetts Institute of Technology (MIT) in Europe, where research in academic institutions fails to transfer to industry efficiently. But as few believed that such an institute could be created in a top-down fashion, and European Union (EU) member states were unwilling to provide major institutional investment, the 'EIT' concept evolved into just a small headquarters. This will select and administer distributed networks of academic institutes and private companies focusing on problems considered most pressing in Europe, such as renewable energy. In the same stroke, the European Parliament inserted the word 'innovation' into the EIT's name, although the original acronym lives on.

The result is an enfeebled EIT that is mismatched with the problems it is designed to solve. The EU has set aside just €300 million (US$475 million) for it in the first six years, a fraction of the minimum of €2.3 billion considered necessary to fulfil the EIT's purpose. It is relying on industry and other sources to make up the difference.

That seems unlikely. But whatever the outcome, the very existence of the EIT concept — and its survival through the rough seas of EU politics — is an indictment of Europe's suffocating national bureaucracies, which have made it impossible for universities and publicly funded research institutes to evolve into MITs on their own. 'Elite' has too often been treated as a dirty word, and interactions with industry considered a betrayal of academic purity. In many countries, including France, Germany and Italy, it is still generally impossible to offer internationally competitive packages to top researchers.

But a belated recognition of the need for change is now taking hold. Important steps have been taken in most countries to develop appropriate legal frameworks and infrastructures for technology transfer. In 2003, both Germany and Italy suggested founding their own 'MITs' — precipitating the same political furore seen later when the EIT was proposed. The Italian Institute of Technology was finally realized in Genoa. In Germany, the idea was quickly abandoned in favour of a plan to encourage existing universities to excel in an MIT-like way. Its competition to award winners the 'élite' title has been a success.

The EIT may yet surprise its critics. Either way, national efforts to boost universities are by far the best way to address the problems that the EIT is intended to solve. ■