nature medicine

Risky business

A recent US Supreme Court ruling places responsibility for the wording of drug labels on pharmaceutical companies. But the task of improving the communication of drug risks does not rest with the pharmaceutical industry alone.

The 4 March ruling by the US Supreme Court in the case of *Wyeth v. Levine* will have major repercussions for the pharmaceutical industry. The verdict allows Vermont musician Diane Levine to collect more than $6 million in damages in a lawsuit she filed against the pharmaceutical giant Wyeth. Levine had sued the company because she had to have part of her arm amputated after receiving an improper injection of Wyeth's antinausea drug, Phenergan, which can cause gangrene if wrongly administered. The jury had found that the company failed to list the dangers of injecting Phenergan directly into a patient's vein on the drug's government-approved label.

The Supreme Court ruling means that oversight of drug labels by the US Food and Drug Administration (FDA) does not protect pharmaceutical companies against liability claims made by patients. The court's decision highlights the need for drug companies to be more forthcoming about the risks associated with their products. But the case also points to the need for system-wide improvements in ways to communicate possible drug side effects.

There is little doubt that, as a result of *Wyeth v. Levine*, patients will be big winners in the courtroom. But they might lose out in the hospital room. The Supreme Court ruling may narrow the drug development pipeline because it could intensify the risk of future lawsuits. No one sues a company for failing to develop a drug. Instead, they go to court over adverse effects from drugs already on the market.

The logical action by drugmakers in the wake of this ruling will be to shift their focus away from putting drugs with potential side effects on the market and toward making medications with safe and predictable effects. In a more litigious climate, companies will perhaps feel more comfortable exploring so-called 'me too' drugs that are structurally similar to known medications.

To keep companies from dropping innovative medicines from their development portfolios, James Copland and Paul Howard of the Manhattan Institute, a corporate-funded think tank, propose creating a compensation program for pharmaceuticals loosely modeled on the Vaccine Injury Compensation Program established by Congress in the mid-1980s. Simply put, for all vaccines recommended by the US Centers for Disease Control and Prevention for routine administration to children, families who feel a vaccine has caused harm do not take the vaccine-maker to trial. Instead, the claimants go before a special court created as part of the compensation program, and any damages they might receive are funded by a tax on vaccines. Adapting this type of system for drugs could perhaps encourage pharmaceutical companies to come forth with details about all possible side effects of their drugs, as the government would help decide when the drugs are to blame for injury.

But to keep companies developing innovative drugs, it will not be enough that they list all possible side effects; they will also need help in getting that information across to doctors with improved systems for communicating and assessing these risks. The emphasis should be placed on developing ways of assessing and averting injuries due to known drug risks on the basis of clinical evidence. Hospitals, for example, can employ high-tech systems that facilitate the safest and most efficacious delivery of drugs. If these technological tools are well designed, they have the potential to make physicians feel more confident about the medicines they choose to administer.

For example, the information technology industry has already developed some tools to guide doctors through the prescription process. So-called 'Computer Physician Order Entry' (CPOE) software asks doctors to enter specific details about each prescription and sends alerts when there is a potential error. Computerized systems are far from perfect, but they have the potential to decrease the number of prescription errors due to inaccurate dosing or indecipherable handwriting. In one report released last year, researchers reviewed more than 1,200 voluntarily reported medical errors. They determined that enhanced electronic prescribing and monitoring tools might have prevented 57% of the 194 errors that related to drugs (*Qual. Saf. Health Care* **17**, 286–290; 2008).

CPOE and other technologies must be developed to better manage drug risks. The bar-coding of medications and the development of automated drug dispensing systems represent two areas of active development. These tools might not only reduce human error but also provide platforms for integrating information about drug risks. The health sector and government should partner with pharmaceutical companies to explore standards for such tools. Technology cannot be the only solution to assessing potential side effects of drugs, but it is one area where various sectors can come together to reduce the threat of these risks.