IN brief

Health under DeParle and Sebelius

America's two new health czars appear ready to push for ambitious healthcare reforms. President Barack Obama in March appointed former Clinton administrator Nancy-Ann DeParle director of the White House Office of Health Reform and nominated Kansas Governor Kathleen Sebelius as secretary of the Department of Health and Human Services (HHS) (Sebelius had yet to be confirmed as *Nature Biotechnology* went to press). DeParle's role is to communicate to lawmakers the White House's approaches to healthcare reform and to negotiate compromises with stakeholders such as insurance providers and drug companies. "Her job is figuring out tradeoffs that all the stakeholders can live with," says Linda Blumberg, a health policy researcher at the Urban Institute in Washington DC. She says DeParle's diverse experience with industry, government and academia may help in those negotiations. DeParle served on the board of device maker Boston Scientific of Natick, Massachusetts, and oversaw Medicare and Medicaid during the Clinton administration. As HHS secretary, Sebelius will be responsible for the US Food and Drug Administration, Medicare and Medicaid and the National Institutes of Health. Sebelius has said health reform will become her "mission" and aims to transform Medicare and Medicaid to focus on prevention. But policy experts say she may lack the close ties with lawmakers to lead reform negotiations. As governor of Kansas, she pushed to allow her state's residents to import drugs from abroad—a hint of one policy she may support in her new role. *Emily Waltz*

Google spawns venture fund

Google, of Mountain View, California, has launched a corporate venture capital arm, Google Ventures, which will be comanaged by entrepreneurs Rich Miner and Bill Maris. Miner has a doctorate in computer science, and Maris' background is in neuroscience. The initial capital amount has not been disclosed, but it's rumored that Google Ventures will spend up to $100 million in the next year. Google spokesperson Andrew Pederson says the fund is not limiting itself "to particular areas right now," but investments are anticipated across a broad range of industries, including healthcare and biotech. The emergence of another funding avenue is welcome, as the life-sciences venture capital sector saw a 15% decline in investment in 2008, according to figures from PricewaterhouseCoopers Money Tree report. Bernat Olle, of Puretech Ventures in Boston, says that "Google does bring to the table lots of cash at a time when other VCs [venture capitalists] are retreating," adding that the internet giant "could be seeing this as a vehicle to gain experience in the biotech field, and perhaps even to keep an eye out for disruptive ideas to its core search business that might come from unexpected fields, such as biotech." *Victor Bethencourt*

preamble, the FDA was invading their space," says Bert W. Rein, a partner at Wylie & Rein in Washington, DC, and one of the attorneys who worked on Wyeth's legal team for the case

"Manufacturers can no longer rely on FDA's claim that preemption right existed all along and is well ensconced in the law," says Aaron Seth Kesselheim, a Boston-based physician who also has a law degree and who has reviewed the case for the *New England Journal of Medicine*. "FDA's attempt to rewrite history and say that this preemption existed has been corrected." In fact, some groups are hoping that medical device makers will also lose the presumption of preemption.

Wyeth v. Levine is expected to have major ramifications, particularly on a wave of similar cases not yet decided, including *Colacicco v. Apotex Inc.* (a generic drug producer) and *Pennsylvania Employees Benefit Trust Fund et al. v. Zeneca* (the London-based pharma). "It [*Wyeth v. Levine*] is without a doubt the most significant case in recent memory involving the prescription drug industry," wrote attorney Brian Currey of O'Melveny & Myers of New York on his company's website. "It may have a lasting impact on many other industries regulated by the federal government as well."

For the pharmaceutical and biotech industries, the first and most obvious impact is likely to be more lawsuits. "Here is a circumstance where a warning was in the label, it was well known to doctors, the drug was inappropriately administered, and yet the Supreme Court still sided with the plaintiff," Gottlieb says.

The decision leaves certain details unclear, such as exactly what Wyeth should have done to avoid a lawsuit. "The Vermont jury simply ruled that the warning wasn't strong enough, but they didn't say they agreed with Levine and that the label should have prohibited IV push, or whether other wording would have been sufficient," Rein says.

The case does show that companies are ultimately responsible for what goes on their drug labels and cannot expect to be shielded from lawsuits based on the FDA review process and drug labeling. "I've heard from lawyers at drug companies already that they cannot rely on the FDA and will need to act unilaterally to respond to this," Gottlieb says.

Still, the case doesn't kill preemption entirely. "Each case will be decided based on its circumstances," said Rein. "The court made it clear that there are cases where preemption will apply." Those are likely only to be cases that involve some topic that the FDA has studied at great length, however, such as the relationship between selective serotonin reuptake inhibitors (SSRIs) and suicidal tendencies. "There has to be a direct conflict between the FDA's findings and the state court's findings," Rein says.

Drug labels are now likely to get more cluttered just as the agency was trying to streamline them. Drug makers will also need to be more vigilant and as forthcoming as possible about potential side effects. The justices asked numerous questions about whether the FDA had carefully considered the risks of IV push and how the agency had decided that doctors should still be allowed to use this option. In the end, the justices clearly felt that a stronger warning was needed.

That puts the agency in a potentially difficult situation, too, because doctors have traditionally argued for more autonomy in prescribing. What's particularly disconcerting from the industry perspective is that Phenergan has been on the market since the early 1950s. "The drug was misadministered, and even then, the risk of this type of incident is probably 1 in 20 million," Rein says. "The jury was looking at that one case. But what about the benefit that millions of people have gotten in the meantime from quicker [nausea] relief?" he asks.

Consumer advocates, such as Kesselheim, counter that the case hinged on what Wyeth knew and how the company acted on that knowledge. "Manufacturers have a responsibility to be very clear and upfront about potential adverse effects related to their products," he says. "In this case, the warning on the label wasn't sufficient, and the manufacturer should have known that."

"Companies were looking for immunity from lawsuits," says Curfman. "That's not in the consumer's best interest."

Others see it differently. "This case illustrates that tragic facts make bad law,"' Justice Samuel Alito noted in his dissent. "The court holds that a state tort jury, rather than the Food and Drug Administration, is ultimately responsible for regulating warning labels for prescription drugs."

Malorye Allison *Acton, Massachusetts*

New product approval

Ixiaro (Japanese encephalitis vaccine, inactivated)	Intercell (Vienna)	The US Food and Drug Administration on March 30 approved Ixiaro to prevent Japanese encephalitis, an infectious disease found mainly in Asia. The vaccine was approved by the European Commission for the same indication on April 2. The vaccine is a purified, inactivated product for active immunization against viral infections of Japanese encephalitis.