

Bruce Burlington, a vice-president of New Jersey drugmaker Wyeth who spent 17 years in senior positions at the FDA, told Kennedy at a health committee hearing on 14 March that his bill was a “thoughtful effort” to balance the twin goals of safety and providing patients with access to new drugs. Still, he said, the law should be less prescriptive, laying out general principles instead of requiring one-size-fits-all plans for risk management.

After the hearing, Burlington said that it is hard to gauge whether the bill would stifle innovation because it is written so broadly that much will depend on how it is administered. Nonetheless, he asserted, it “may end up freezing drugs out of development”.

Another concern about the bill was voiced at the same hearing by Senator Tom Coburn (Republican, Oklahoma), a member of the health committee who is also a practicing obstetrician and gynaecologist. Coburn charged that as written, the bill would allow the FDA to forbid doctors from prescribing high-risk medicines for conditions other than those for which they are approved — an interpretation that Kennedy disputes. “The problem I see is that the FDA is going to be interfering with the practice of medicine,” Coburn said.

Corrupting influence

At the other end of the political spectrum, a group of 21 academics and clinicians led by former FDA official Susan Wood of George Washington University in Washington DC is calling on Congress to throw out the entire user-fee law, claiming that it corrupts the agency. In a letter to Congress, the group wrote that the existing law “has helped to foster the public’s perception that industry has become the primary client of the FDA, rather than the American people.” They are calling on Congress to fund the whole of the FDA directly. That is something few expect to happen, for cost reasons.

For its part, the drug industry argues that the FDA just needs the resources to use the muscle it already has. Industry lobbyists note that the FDA’s own recommendations for the new user-fee bill — submitted last month — would triple the user fees now directed to post-market safety, to \$150 million over five years. That would allow the agency to hire 82 new employees. Another, entirely new user fee would allow it to hire 27 workers to vet direct-to-consumer drug advertisements before they run.

The PhRMA agreed to fund this expansion in closed-door negotiations with the regulator last year. “We think it provides the FDA with pretty much everything they need to address drug safety,” says Lassman. The legislation that must pass by September will reveal whether Congress agrees. ■

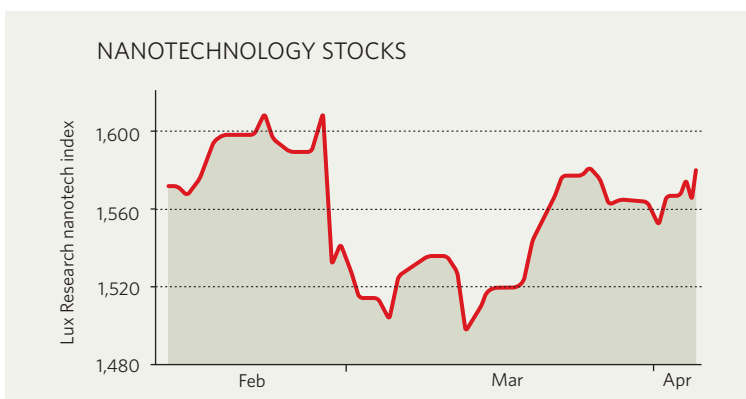
IN BRIEF

MULTIPLE WAFER IBM says that it has developed a three-dimensional silicon chip. The computer company said that its technology, which uses tiny metal wires to connect silicon chips tightly stacked on top of each other, will enable it to pack more functionality into its products. A device based on the concept will debut in power chips in some of IBM’s wireless devices later this year, and then spread to more general application.

STOCK-MARKET GOAL Russian drug company Pharmstandard is planning to float on the London and Moscow stock exchanges in June. The company sells generic drugs and is one of Russia’s leading pharmaceutical companies. It has been valued by some analysts at around US\$1.5 billion, and it will be the largest Russian drug company so far to float on international markets. Pharmstandard, which is part-owned by Roman Abramovich, the billionaire owner of Chelsea Football Club, has annual sales of about \$320 million in the fast-growing Russian pharmaceutical market.

REAGENT MERGER Agilent Technologies, a manufacturer of scientific instruments based in Santa Clara, California, said that it would buy the biotechnology company Stratagene for around \$246 million. Stratagene, which is based in La Jolla, California, develops clinical diagnostics and reagents and will be incorporated into Agilent’s life-sciences unit if, as expected, shareholders approve the deal. The acquisition is set to boost Agilent’s standing in the growing molecular-diagnostics market. Stratagene’s stock rose \$2.20 to \$10.71 after the deal was announced on 6 April, and Agilent’s stock went up 35 cents to \$35.06.

MARKET WATCH



Major stock indices got the jitters in late February over the short-term outlook for the US economy. But nanotechnology stocks, as measured by the Lux Research nanotech Index, held up quite well — and some companies had substantial gains.

Much of the general market concern is over a possible weakness in consumer demand if house prices in the United States continue to stagnate. But revenue for nanotechnology companies remains dominated by demand from businesses (in equipment and materials, for example), rather than from consumers, explains Peter Hébert, chief executive of New York-based Lux Research, which compiles the index. So the index has fared reasonably well, outperforming the high-tech Nasdaq index so far this year.

There has been no clear, general trend in the index over the past two months, but a few star stocks have performed well.

Arrowhead of Pasadena, California, for example, pleased its investors with several acquisitions, including that of Carbon Nanotechnologies, the carbon nanotubes company founded by late Nobel laureate Richard Smalley. Arrowhead’s shares soared from US\$3.75 in mid-March to \$4.95 last week.

Los Angeles drug-delivery specialist Abraxis Bioscience, whose main product is a nanoparticle-borne breast-cancer drug Abraxane, also rose in value after announcing 2006 sales of \$765 million, up from \$520 million the previous year.

Hébert says that overall, confidence in the nanotechnology sector remains strong, and has been driven by growing global investment during 2006 — \$6.4 billion in public research, \$5.3 billion in corporate research and development and \$650 million in venture capital. ■

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