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not be an issue. But in cancer, “you’re dealing with dying patients,” says Cy Stein, an oncologist at Albert Einstein College of Medicine in New York. “In phase I, at least we can tell them: ‘We really think we’ve got something here.’” But in phase zero, he says, “you’re offering nothing. I can’t agree to that. Certainly not to save big pharma some time.”

Others, including Sidney Wolfe, director of the health-research arm of Public Citizen, a Washington-based advocacy group, have argued that phase zero studies are ethically troublesome. By reducing the preclinical testing required before an experimental drug goes into humans, says Wolfe, the FDA “increases the risk to the subjects”.

Senator Chuck Grassley (Iowa, Republican) put it more bluntly in a statement when the regulations were released. “The FDA is loosening the reins on drug companies,” he said. “I’m concerned for those who will be receiving these experimental drugs.”

But Woodcock says the approach will protect patients. “Study in people early in the process is going to decrease human exposure to compounds that ultimately fail,” she says, “Which right now is the majority of them.”

Curiel, for his part, hopes to capitalize on the manufacturing changes, cannibalizing the first-class hardware and equipment of his white-elephant facility and moving it to a corner of his existing lab. Complying with the old rules was “complicated, difficult and time-consuming,” he says. “The new guidelines will make all of this dramatically easier.” ■

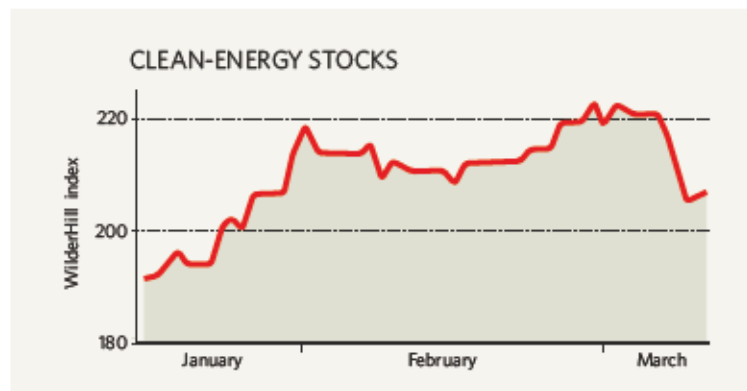
IN BRIEF

UNLUCKY DIP Shares in Human Genome Sciences, the Maryland biotechnology company founded by William Haseltine, tumbled after it announced mixed results from trials of its most promising drug candidate, the hepatitis C treatment *Albuphron*. The company said that the drug’s performance exceeded that of the current market leader, Roche’s *Pegasys*, in patients who took it every two weeks — but not in those who took it once a month. Analysts said the result would lessen the drug’s sales potential, and the company’s shares dropped \$2.80 to \$11 on the news.

FREE RIDER Microsoft has applied to re-register two of its Irish subsidiaries as ‘unlimited liability’ companies — which won’t have to declare any financial results — after coming under fire for allegedly using them as tax shelters. The two companies, Round Island One and Flat Island Company, operate out of small offices in Dublin. They are said to own much of the software company’s intellectual property, and between them reported profits of more than \$4 billion in 2004. The US Treasury is planning to tighten its rules on US companies that hoard their intellectual property in foreign countries that have low corporate tax rates.

CONTRASTING FORTUNES Biochemist Arthur Levinson, the chief executive of Genentech, earned \$69 million last year after cashing in some stock options, the company reported. Three other managers at the thriving California biotechnology company also got more than \$20 million each. But some bosses do it for the love alone: Apple Computer’s chief executive Steve Jobs sat on his options in 2005, and his compensation package for the year was a nominal salary of one dollar — the same as the year before.

MARKET WATCH



January 2006 featured an unexpected endorsement of clean energy by the president of the United States.

But although shares in clean-energy companies reached their highest level since 2001 around the time of George W. Bush’s State of the Union address, they then fell back somewhat.

The WilderHill index, which tracks clean-energy firms that are listed on stock markets in the United States, enjoyed strong growth through 2005 and rose by more than a quarter in the month of January, before slipping back in early March.

Robert Wilder, whose company compiles the index, said that the slip was due partly to shareholders cashing in their profits, and partly to a slump at Distributed Energy Systems, a company that integrates power from different sources. Shares in the Connecticut-

based firm fell by a third on 8 March after it issued a weak earnings forecast.

But Michael Liebrich, head of London-based New Energy Finance and a member of the index’s advisory board, says the fundamentals of the sector remain powerful. “In 2005, there was US\$44 billion of investment in renewable energy worldwide — about 7% of all energy investment,” he says bullishly. “In which direction is that going to go?” He thinks it can grow fivefold in ten years.

And although Wilder sees Bush’s speech as significant, he says that solid financial progress — exemplified by the \$125-million contract that Evergreen Solar of Massachusetts won from a German wholesaler on 15 March — is the source of the sector’s strength.

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