

## Norman Latker

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**Sent:** Monday, December 20, 2004 9:33 AM  
**To:** Norman Latker  
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News Analysis: Pricey Drug Trials Turn Up Few New Blockbusters

December 18, 2004  
By ALEX BERENSON

The worldwide drug industry is ailing.

Three major drug companies - Pfizer, AstraZeneca and Eli Lilly - each disclosed serious problems with important medicines yesterday, throwing a spotlight on the fact that the \$500 billion drug industry is stumbling badly in its core business of finding new medicines.

The decline in drug research and development has been an open secret among analysts and scientists for years. But drug company executives have insisted that their industry is fundamentally healthy and their expensive research efforts will pay off.

They have tried, meanwhile, to offset their weakness in creating profitable new drugs by pursuing aggressive campaigns to market existing drugs to doctors and patients, impose big price increases and make efforts to extend patents on existing medicines. Those tactics have protected their profits but irritated consumers and governments that pay for drugs, causing a political reaction in the United States and Europe.

After yesterday's news, the intensity of that reaction

s likely to increase.

less than 12 hours, Pfizer said that it had found increased risk of heart problems for people taking celebrex, a painkiller that is one of the world's best-selling medicines. AstraZeneca reported that a trial of Iressa, a lung cancer drug approved in the United States last year, showed that the drug did not prolong lives. And Eli Lilly warned doctors that Strattera, its drug to treat attention deficit disorder, usually in children, had caused severe liver injury in at least two patients.

Investors punished all three companies, sending Pfizer stock down 11.2 percent, AstraZeneca down 7.7 percent and Eli Lilly down 2.4 percent. Collectively, the declines reduced the market value of the three companies by more than \$30 billion, worsening the industry's weak performance this year.

The sequence of events is a sign that the companies must confront their difficulties in finding new drugs, said Richard T. Evans, an analyst at Sanford C. Bernstein, a Wall Street research firm.

"Their R.&D. productivity is just terrible," he said.

No major drug company is exempt from the problem. The number of new drugs approved by the Food and Drug Administration has declined sharply since the mid-1990's, falling from 53 in 1996 to 21 in 2003, even as the industry has nearly doubled its annual spending on drug development, to about \$33 billion.

Complicating the process, many drugs already on the market do a reasonably good job, so the bar that new therapies must cross is high, especially because most are expensive.

If companies cannot reverse the trend, investors will almost certainly demand that they cut their research spending. Meanwhile, governments, faced with growing drug costs for publicly financed programs like Medicare and Medicaid, may well alter regulations on drug marketing or force the companies to cut prices, Mr. Evans said. A result in the long run may be an industry that is less profitable and less able to produce new drugs for patients.

Still, experts note that progress comes in fits and starts and the flood of newly discovered biomedical information could lead to many new drugs. But traditional drug companies have not yet had much luck with biotechnology, though they have licensed some drugs from biotechnology companies.

While they struggle with new technologies, the companies are facing a steady stream of patent expirations on their most profitable drugs. To combat that, Pfizer and some other companies have used mergers or acquisitions to grow. But those deals do nothing to increase their overall ability to produce new medicines, critics say, and may even hurt the industry as merging companies struggle to integrate their laboratories.

Dr. Jerry Avorn, professor of medicine at Harvard Medical School and author of "Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs" (Knopf, 2004), said the absence of new drugs had caused companies to try to

stoke demand for their existing medicines by marketing them directly to consumers.

"If you don't have a lot of breakthrough drugs in your pipeline, and you're a company, you need to market the hell out of the drugs that you do have," Dr. Avorn said. As a result, many people are taking drugs that have only a moderate benefit for them, or no benefit at all, he said.

At the same time, companies are not closely monitoring the side effects of the medicines that they already sell, because they fear that information about side effects will discourage patients from using new medicines, Dr. Avorn said.

On the surface, the industry seems relatively healthy. Sales are rising strongly both in the United States and worldwide, with revenue up about 9 percent in 2003, to more than \$490 billion, according to IMS Health, which tracks drug sales.

And the industry is highly profitable. Excluding one-time charges, Pfizer is expected to earn more than \$14 billion this year on sales of \$51 billion, a profit margin among the highest of any big company.

Pfizer did get some good news yesterday. Federal regulators approved Macugen, developed by Eyetech Pharmaceuticals Inc. and Pfizer to treat macular degeneration, which causes blindness in the elderly.

Major drug companies have increased research spending. Pfizer spends \$7 billion a year on research, according to its filings.

That level of research spending justifies the high prices of many medicines, drug company executives say. Any effort to cap prices, they say, may compromise the discovery of new drugs.

In the 1990's, the companies were able to bring several major new categories of drugs to market. But in this decade, companies have had few major breakthroughs.

Until this year, Wall Street had been relatively patient with the industry, viewing it as a profitable and stable place to invest.

But in the last few months, investors have begun to turn away from the sector. A broad index of pharmaceutical stocks has fallen 7.4 percent this year, while the Standard & Poor's 500-stock index has risen 7.4 percent. The companies that made yesterday's announcements have been among the worst performers this year, with Pfizer shares down 30 percent, AstraZeneca off 22 percent, and Eli Lilly down 20 percent.

There is no simple way to make drug research more productive, said Dr. K. Arnold Chan, a professor at the Harvard School of Public Health. The amount of basic biomedical knowledge has vastly increased in the last few years, but scientists have not yet been able to translate that information into new medicines.

"There's a gap between basic science and clinical science," he said.

Dr. Chan said he hoped the problems were merely a dry spell in a long period of advances.

"If we take 30 years, you could see a lot of progress," Dr. Chan said. "We saw a lot of promise in the 1990's. But the last couple of years have been pretty pathetic."

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