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## New technology reduces the profitability for new drugs

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HOUSTON The annual American College of Cardiology meeting last month provided a striking example of how combinatorial chemistry is changing the face of the drugs market. At the conference, clinical trial results for a new statin drug - AstraZeneca's Crestor (rosuvastatin) - were reported in a series of papers. AstraZeneca is expected to file for US and European regulatory clearances and hopes to bring the product to market in 2002. If so, this will bring the number of statin drugs on the market to seven, less than six years after commercialization of the first one. It is this shift in pace of the new drug development process that is effectively fragmenting the drugs market.

Statins are widely acknowledged as being effective in substantially lowering blood cholesterol levels by reducing the liver's production of cholesterol. The total market for products that reduce blood cholesterol levels in 2000 was \$15.9 billion. Instead of one statin dominating this market, however, six products share it: Pfizer's Lipitor (atorvasatin) leads with 2000 sales of \$5.8 billion, followed by Merck's Zocor (simvastatin) with \$5.3 billion. Bristol-Myers Squibb's Provachol, Bayer's Baycol, Novartis' Lescol and Merck's Mevacor have smaller market shares. According to David Orloff of the US Food and Drug Administration's division of metabolic and endocrine drug products, these statin drugs all have similar effectiveness and safety profiles.

Even though the overall market for statin drugs grew 20% last year and Lehman Brothers drug industry analyst Tony Butler predicts sales growth to be 12% annually over the next several years, with seven statin drugs dividing the market, sales growth for each drug is unlikely to be dramatic.

The statins are only one example. The speed of development of new drugs in the same therapeutic class as existing patent-protected drugs - largely because of combinatorial synthesis and high-throughput screening - means that early competition between drugs is becoming far more common. As a result, generic competitors are no longer the market limiter for a high-value, high-profit innovative drug.

Should we feel sorry for drug companies facing this type of competition early in the life cycle of a drug? They still stand to make billions from new drugs, as the examples of Pfizer's Lipitor and Merck's Zocor indicate. But this new type of competition makes it less likely that each new drug will achieve the high sales and profits of previous 'blockbuster' drugs, whose patents are now expiring.

For example, AstraZeneca had hoped Crestor would fill the profits gap when ulcer drug Losec and heart drug Zestril face generic competition in 2001 and 2002, respectively. But this is unlikely, as worldwide sales of Losec and Zestril amounted to more than \$7 billion last year and the consensus among pharmaceutical industry analysts is that Crestor should achieve peak sales of only \$3.1 billion.

Drug companies will have to either greatly increase their research and development programmes to maintain current profit levels, or become accustomed to the more modest profit levels characteristic of many other industries. Despite the current craze for drug company mergers, aimed at keeping new drug development pipelines full, the drugs market may well become increasingly fragmented. This would mean opportunities for smaller drug firms to compete but also that consumers should benefit from lower drug prices even before drugs go off patent.

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