

BIOBUSINESS BRIEFS

MARKET WATCH

Forecasting market share in the US pharmaceutical market

Drug development is costly, and so drug makers need accurate estimates of sales potential. However, sales forecasts are often unreliable (*Nat. Rev. Drug Discov.* 12, 737–738; 2013). Here, we present an analysis of data concerning entry order and promotional spending from a large sample of drug classes, to estimate peak market share while controlling for product quality (see [Supplementary information S1 \(box\)](#) for details of the data and analysis methods).

The data sample included new molecular entities approved by the US Food and Drug Administration (FDA) between 1988 and 2009. We ended the sample at 2009 approvals so that each assessed product would accrue at least 4 years of post-launch data on sales and promotion. To control for product quality, we focused on drugs for which the FDA granted a standard review (meaning that the drugs did not represent a significant advance

over previous drugs) and that the French Transparency Commission classified as providing little or no improvement over previous drugs (see the [Haute Autorité de Santé](#) link in Further information). The sample comprised 29 second entrants to a particular drug class, 13 third entrants and 8 fourth entrants.

To estimate the impact of the share of promotional spending, order of entry and time to market on peak market share, we used an ordinary least-squares regression to determine the coefficients in our econometric model, which is shown in FIG. 1a. The dependent variable was peak share, which we defined as the maximum monthly share reached by a new entrant during the first 4 years on the market. The independent variables were the share of promotional spending, order of entry, time to market and whether further competitor

drugs entered for second entrants. The share of promotional spending was calculated as the ratio of the new entrant's promotional spending to the total promotional spending from all products in the therapeutic area during the first 12 months post-launch, including spending on physician or nurse detailing, advertising in journals, events and direct-to-consumer advertising.

We measured time to market — relative to the most recent entrant on the market — in quarters. For a more complete description of the methods, identification strategy and alternative specifications, please see [Supplementary information S1 \(box\)](#).

The main effects of changes in the assessed variables in the model were as follows. First, an increase of one percentage point in promotional share was associated with an increase of 0.46 percentage points in peak market share. Second, relative to a second entrant, peak market share was 18 percentage points lower for a third entrant and 23 percentage points lower for a fourth entrant, even if they had the same promotional spending. Third, for a second entrant, each additional delay of one quarter led to a decrease of 0.9 percentage points in the peak market share. The impact of a delay for a third or fourth entrant was smaller. Fourth, the launch of a third entrant reduced

$$\mathbf{a} \quad \text{peak_share} = 0.23 + (0.46 \times \text{promotional_share}) - (0.18 \times \text{third}) - (0.23 \times \text{fourth}) - (0.009 \times \text{time}) + (0.007 \times \text{time} \times \text{third}) + (0.01 \times \text{time} \times \text{fourth}) - (0.06 \times \text{new_competitor})$$

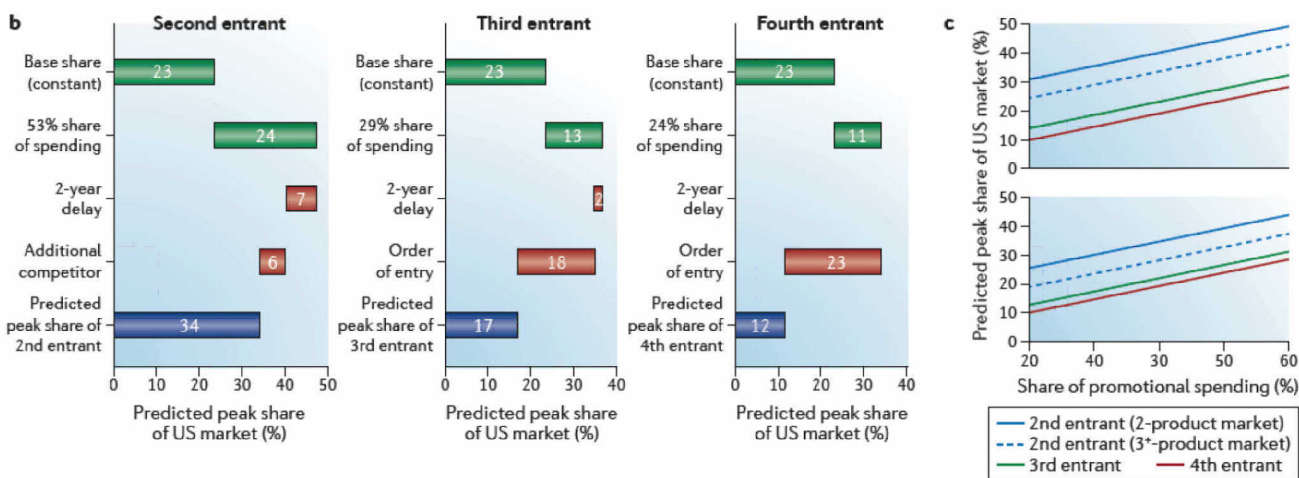


Figure 1 | Forecasting the market share of drugs in the US market.

a | Econometric model of peak market share, with coefficients determined by ordinary least-squares regression. Peak share was defined as the maximum monthly US market share reached by a new entrant over the first 4 years on the market, and the share of promotional spending was defined as the ratio of the new entrant's promotional spending over the first 12 months post-launch to the total promotional spending in the therapeutic area. We included indicator variables for third and fourth entrants (named third and fourth respectively), so for second entrants, third = fourth = 0. The variable 'new_competitor' had a value of 1 if a second entrant

faced a third entrant. **b** | The effect of promotional spending, delay and number of competitors on peak market share for a second entrant (left panel), third entrant (middle panel) and fourth entrant (right panel). **c** | Peak market share as a function of order of entry, share of promotional spending and launch of a third entrant (for a second entrant) for products launched 2 quarters (top panel) or 8 quarters (bottom panel) after the previous launch. The sales data are from the IMS Health US National Prescription Audit from IMS Health, and the promotional data are from SDI Health. For a more complete description of the methods, identification strategy and alternative specifications, see [Supplementary information S1 \(box\)](#).

the peak market share potential of second entrants by 6 percentage points; entry of a fourth competitor did not have a statistically significant effect on the third entrant.

Given estimates of the value of reduced time to market, we can also calculate the value of a priority review voucher, which decreases FDA review time from about 10 months to 6 months. Previous estimates of voucher value were based on the value gained by shifting existing sales earlier in time; however, we show that having an earlier launch also increases peak market share. For example, if the second entrant reached the market 4 months earlier, peak market share would increase by 1.2 percentage points, or US\$12 million in the peak year for a US\$1 billion market (in addition to the value of shifting sales earlier).

FIGURE 1b summarizes the determinants of peak share. The assumptions used for the baseline share of promotional spending were

the average shares for the products in our sample (53% for a second entrant, 29% for a third entrant and 24% for a fourth entrant; see Supplementary information S1 (box)). For a second entrant (left panel), peak share was 34%, assuming 53% promotional share, a 2-year delay in reaching the market, and a new entrant later. For a third entrant (middle panel), the peak share was 17%, because it was a later entrant and had less promotional spending. The peak share was 12% for a fourth entrant (right panel).

FIGURE 1c illustrates the impact of promotional share, order of entry and the launch of a third entrant on the predicted peak market share of a second entrant. In the top panel of the FIG. 1c, the products are assumed to be launched 6 months after the previous launch in the market. In the bottom panel, the products are assumed to be launched 2 years after the previous launch in the market.

Forecasting a drug's peak market share is challenging. We hope that the model presented in this paper will give managers additional insights about the future success of investigational drugs.

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The authors declare competing interests: see Web version for details.

FURTHER INFORMATION

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SUPPLEMENTARY INFORMATION

See online article: S1 (box)

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