

Forecasting Market Share in the United States

Pharmaceutical Market

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Due to space constraints in the journal, most of the details about the analysis are in the appendix (beginning on page 7).

Introduction

Drug development is costly,^{1,2} so drug makers need accurate estimates of sales potential. However, sales forecasts are often unreliable.³ 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.

Data and Methods

The data sample included new molecular entities approved by the US Food and Drug Administration (FDA) from 1988 to 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 which the FDA granted standard review (meaning that the drugs did not

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represent a significant advance over previous drugs) and that the French Transparency Commission classified as providing little or no improvement over previous drugs.⁴ The sales data came from the IMS Health US National Prescription Audit from IMS Health, and the promotional data came from SDI Health.

We used an ordinary least-squares regression. 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 share of promotional spending,^{5,6} order of entry,^{7,8} time-to-market, and whether new competitors entered for second entrants. We calculated the share of promotional spending 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, where promotional spending included physician/nurse detailing, journals, events and direct-to-consumer advertising. We measured time-to-market in quarters relative to the most recent entrant on the market. 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* equaled 1 if a second entrant faced a third entrant.

For more details about the methods, identification strategy, and alternative specifications, please see the appendix.

Results

Our sample comprised 29 second entrants, 13 third entrants and 8 fourth entrants. We estimated peak market share as follows:

$$\begin{aligned} \text{peak_share} = & 0.23 + 0.46 \text{ promotional_share} - 0.18 \text{ third} - 0.23 \text{ fourth} - 0.009 \text{ time} \\ & + 0.007 \text{ time*third} + 0.01 \text{ time*fourth} - 0.06 \text{ new_competitor} \end{aligned}$$

Promotional share. An increase of one percentage point in promotional share was associated with an increase of 0.46 percentage points in peak market share.

Order of entry. 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.

Time-to-market. For a second entrant, each additional delay of one quarter led to a peak market share decrease of 0.9 percentage points. The impact of a delay for a third or fourth entrant was smaller.

New competitor. The launch of a third entrant reduced 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.⁹ 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 drug (in addition to the value of shifting sales earlier).

Figure 1 summarizes the determinants of peak share. The promotional share assumptions used were the average share in our sample (i.e. 53% for a second entrant, 29% for a third entrant and 24% for a fourth entrant, see Table 1 in the appendix). For a second entrant (the top panel of the figure), 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 (the middle panel of the figure), the peak share was 17 percent, because it was a later entrant and had less promotional spending. The peak share was 12 percent for a fourth entrant (the bottom panel of the figure).

Figure 2 illustrates the impact, on market share, of promotional share, order of entry, and the launch of a third entrant on the share potential of a second entrant. In the top panel of the figure, the products are assumed to be launched 6 months (2 quarters) after the previous launch in the market. In the

bottom panel of the figure, the products are assumed to be launched 2 years (8 quarters) 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.

Disclosures

Stephane A. Régnier is an employee of Novartis Pharma AG. The views in the article are those of the authors, not necessarily those of Novartis Pharma AG.

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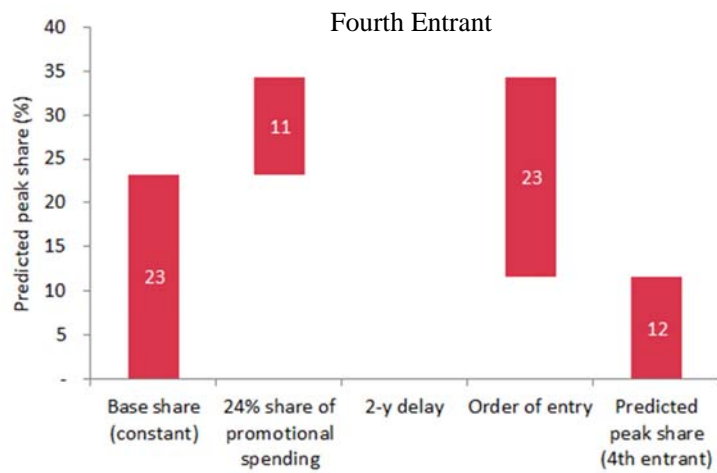
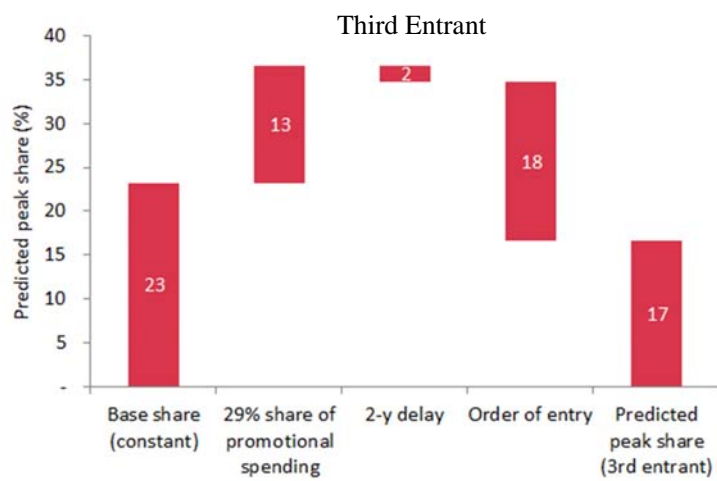
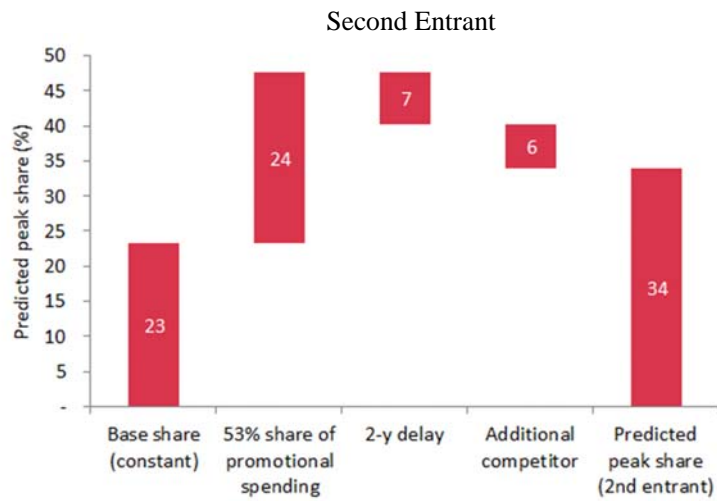


Figure 1. The effect of promotional spending, delay and number of competitors on peak market share for a second entrant (top panel), third entrant (middle panel) and fourth entrant (low panel).

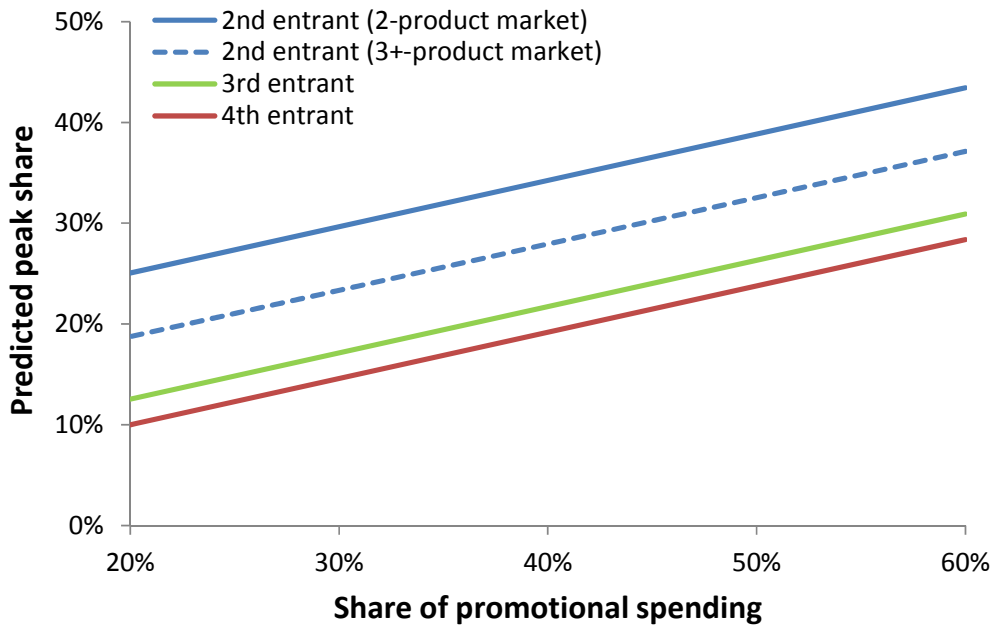
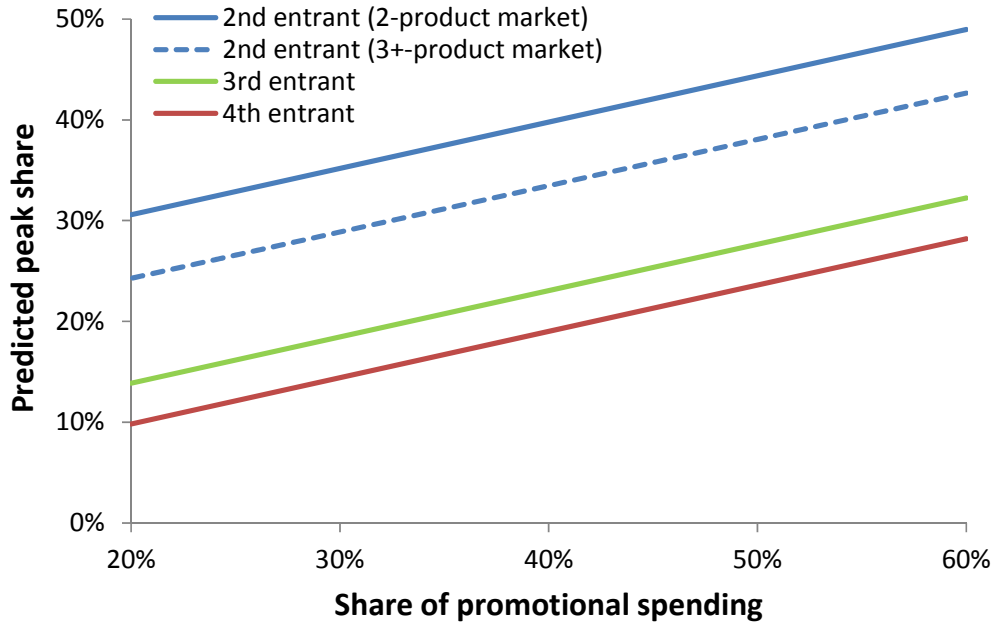


Figure 2. Peak market share as a function of order of entry and share of promotional spending for products launched 2 quarters after the previous launch (top panel) and 8 quarters after the previous launch (bottom panel).

Appendix

1. Data

The sample included new molecular entities approved by the US Food and Drug Administration (FDA) from 1988 to 2009. We ended the sample at 2009 approvals so that we would have four years of sales and promotion following launch. We identified drugs for the sample using the universe of FDA approvals between 1999 and 2009¹ and annual reports from the 20 leading pharmaceutical companies from 2007 to 2009. We excluded drugs primarily used in hospitals and clinics, because our sales data were collected from retail pharmacies. We also excluded priority drugs, focusing on drugs receiving standard FDA review (meaning that they did not represent significant advances over previous drugs) and received an Amélioration du Service Médical Rendu rating of IV (minor improvement in terms of efficacy or safety) or V (no improvement) by the French Transparency Commission.² Finally, we excluded drugs in classes with generic competition. The list of drugs included in the analysis appears in Table S1.

1.1. Missing data

If total prescriptions in the fourth year were not available (e.g. Allegra [fexofenadine], Astelin [azelastine], Diovan [valsartan], Zyprexa [olanzapine], Zyrtec [cetirizine]), we calculated peak share using prescriptions in the fifth year and, when available, with prescriptions in the third year.

If the ratio of total company pharmaceutical revenue to total pharmaceutical revenue of competing companies was not available in the calendar year before drug launch, we used the ratio in the year of launch (Femara [letrozole], Lescol [fluvastatin], Seroquel [quetiapine], Zomig [zolmitriptan]) or in the year after launch (Prinivil, Requip [lisinopril]).

We did not have data from the amélioration du Service Médical Rendu (ASMR) ratings for Pravachol (pravastatin), Astelin (azelastine), Detrol+LA (tolterodine) and Enablex (darifenacin). We used our

judgment to classify those products as me-too. We also used our judgment to classify Actonel (risedronate) as a me-too even though the product received an ASMR of III (modest improvement).

1.2. Combinations

The sales and promotional spending of Cialis (tadalafil) (launched in November 2003) and Levitra (vardenafil) (launched in August 2003) were combined into a product called Cialis+Levitra (tadalafil+vardenafil). Similarly, the sales and promotional spending of Metadate CD (Methylphenidate) and Adderall XR (amphetamine mixed salts) were combined.

1.3. Co-promotions

When products were co-promoted by two pharmaceutical companies, the higher revenue of the two firms was used to calculate ratio of total company revenue to total revenue of competing companies. The list of identified co-promotions is available on request.

1.4. Me-too classification

Three products (Actos [pioglitazone], Reyataz [atazanavir] and Vioxx [rofecoxib]) were classified as 'me-too's even though they received priority review by the US Food and Drug Administration because the HAS did not find meaningful clinical differentiation vs the first entrant. Actos and Vioxx shared the priority review status of the first entrant because they were launched within 6 months of the first entrant.

Five products were excluded even if they received an ASMR of IV or V due to unusual circumstances (such as inferior delivery device, multiple drugs sold by the same company in a therapeutic class, etc.). Including those eight products in the model reduced the precision of the model (R^2 of 0.74 instead of 0.89) but did not change the conclusions. The analysis including the excluded products is available on request. Three products (Pylera, Tyzeka and Uroxatral) were not included because their ASMR ratings were not retrieved.

2. Methods

To estimate the impact of the share of promotional spending, order of entry and speed-to-market on peak market share, we used an ordinary least-squares regression.

In the econometric model, an observation is a drug.

$$\begin{aligned} peak_share_i = & \beta_0 + \beta_1 promotional_share_i + \beta_2 third_i + \beta_3 fourth_i + \beta_4 time_i \\ & + \beta_5 time_i third_i + \beta_6 time_i fourth_i + \beta_7 new_competitor_i + \varepsilon_i \end{aligned} \quad [1]$$

$$\varepsilon_i \sim N(0, \sigma^2)$$

$$peak_share_i = \text{Max}_{t \leq 48} \frac{Q_{it}}{\sum_{k \in m} Q_{kt}}$$

$$promotional_share_i = \frac{\sum_{t=1}^{t=12} A_{it}}{\sum_{t=1}^{t=12} A_{kt}}_{k \in m}$$

where $peak_share_i$ is the peak share of prescriptions Q_{it} for product i in month t over the first 4 years after launch in market m (discussed in the “3.3. Accuracy and generalizability of the results” section). Similarly, $promotional_share_i$ is the share, over the first 12 months, of advertising A_{it} (including resources spent on physician/nurse detailing, journals, events and direct-to-consumer advertising) of product i in month t . Order of entry is modeled with $third_i$ and $fourth_i$ which are dichotomous variables for third and fourth entrants (the second entrant is the default). Time-to-market is $time_i$, which is the time difference between the launch of product i and the most recently launched product in the category. This measure was used because delay versus first entrant is correlated with the order of entry. Note that the time-to-market variable is capped at 14 quarters (cut-off value set based on data fit) meaning the potential impact of a delay is capped). $new_competitor_i$ is a dichotomous variable indicating whether a second entrant faced new competition from a third entrant within the first 4 years on the market. ε_i is the unobserved error term and is assumed to be independent of m . The coefficients of equation [1] were estimated with an ordinary least-squares regression. Regressions were run using the statistical analysis programs Stata 12.0 (StataCorp LP, College Station, TX, USA).

Peak market share and peak sales are widely-used success metrics in the pharmaceutical and financial analysis industries. When products launched in the same quarter (e.g. Actos [pioglitazone]/Avandia [rosiglitazone]; Prinivil/Zestril [lisinopril]), average share over 4 years was used instead of the maximum monthly share reached over the first 4 years. We chose four years (48 months) for measuring peak market share for two reasons. First, having a shorter time frame allowed the inclusion of drugs that were approved as recently as 2009. Second, using a short duration did not prevent the generalization of the results. In fact, previous studies demonstrated that the sales level in the first nine months after launch determines 81% of the variance in sales over the lifespan of a product.³

2.1. Identification

One major methodological concern with estimating the effect of promotional spending and other factors is that they may be correlated with unobserved characteristics of the product. For example, if the drug is high quality relative to competitors, and the manufacturer promotes the drug more as a result, then we will overestimate the effect of promotional spending on market share, wrongly assuming that the high market share was due to promotion rather than due to quality.

Fortunately, the nature of the regulatory process allows us to eliminate quality extremes. Products that are much lower quality than competitors are not approved by regulators. Products that are much higher quality than competitors (as measured by US and French regulators) were not included in our sample.

A further methodological challenge was accounting for the direction of causality; that is, whether sales depend on promotion, or promotion depends on expected sales.⁴ This potential issue was again mitigated by considering only drugs that had no significant improvements over previous drugs. For those drugs, it is unlikely that manufacturers have private information and forecast the success/failures of drugs and set promotional spending at launch accordingly.

To further address concerns about causality, we used instrumental variables that affect promotional spending but not product quality or market share. We conducted a two-stage least-squares regression

followed by an endogeneity test (endogtest in ivreg2 command in Stata based on Sargan–Hansen statistics). In the first stage, we hypothesized that larger companies have more resources and, as a consequence, have a larger share of promotional expenses than smaller firms. We also assumed that a US location of company headquarters for new entrants and first entrants could potentially impact the level of promotional spending.⁵ We assumed that there was no direct effect between firm size and peak share (other than through higher promotional expenses). The endogeneity test described in the next section did not find evidence of endogeneity.

2.2. Finite sample assumptions validation

The model relies on least-square estimates with a small number of observations, so we used the following tests to ensure ordinary least-square assumptions for finite samples were not violated: (1) Link–Ramsey Regression Equation Specification Error Test (RESET) (functional form of the conditional mean). (2) Breusch–Pagan and Park tests (homoscedasticity); (3) Shapiro–Wilk W test (normality of residuals); (4) variance inflation factor (VIF) (absence of multicollinearity); and (5) residuals versus predicted value analysis (exogeneity).

3. Results

Order of entry, time-to-market, promotional spending, and launch of additional competitors were all statistically significant variables (Table S3). The impact of each variable is described in the article. Figure 1 in the main article illustrates the impact on market share of promotional share, order of entry, and the launch of a third entrant. Figure 1b summarizes the determinants of peak share. The promotional share assumptions used were the average share in our sample (that is, 53% for a second entrant, 29% for a third entrant and 24% for a fourth entrant, see Table S2). For a second entrant (the left panel of Figure 1b), 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 (the middle panel of Figure 1b), the peak share was 17 percent, because it was a later entrant and had less promotional spending. The peak share was 12 percent for a fourth entrant (the right panel of Figure 1b). The impact of a delay by order

of entry is shown in Figure S1. A 6-month delay is associated with a peak share reduction of 1.8-percentage point for a second entrant (vs. 0.4 point for a third entrant)

3.1. Identification

The results from the two-stage least-squares regression appear in Table S4. The coefficients and significance levels are similar to those in the base case. It was not possible to reject that the share of promotional spending was exogenous ($p = 0.60$). Therefore, there is limited risk that our model suffers from endogeneity issues.

We ran several tests to assess the validity of the instruments. The Hansen J statistic was 1.63 ($p = 0.44$). Therefore, we cannot reject the hypothesis that the instruments are valid instruments, i.e. uncorrelated with the error term. In addition, the instruments were not weak (partial R^2 of excluded instruments of 0.33 with an F-value of 8.6).

3.2. Finite sample assumptions validation

The ordinary least-square finite sample assumptions do not appear to be violated based on the results from the Link–RESET, Breusch–Pagan, Park and Shapiro–Wilk W tests ($p = 0.96$, $p = 0.16$, $p = 0.10$ and $p = 0.14$ respectively). The highest VIF value was 4.8 and we found no patterns between residuals and predicted values.

3.3. Accuracy and generalizability of the results

For 38 products, the values of predicted and actual peak share differed by fewer than 5 percentage points (Figure S2). The median error (in absolute terms) in prediction was 2.9 percentage points (median actual share is 25.0%). Expressed as a percentage of sales, the median error of prediction was 14.7%. Details below also show that the ordinary least squares regression assumptions were not violated. The strength of the model resides in the comprehensiveness of the variables explaining share. For instance, the model explains much of the variance for peak shares (adjusted R^2 is 0.87). Therefore, most, if not all, relevant variables are included in the model.

We also investigated whether the results could be generalized outside the selected sample, because the number of explanatory variables was large relative to the number of observations. If the model is too complex, there is a risk that the model could not be valid outside the sample. We tested if it was the case in the current model by conducting a Copas test. In this test, we split the observations in two samples of equal sizes, A and B. Then, we estimated the coefficients of our model using the observations from sample A. We used those coefficients to predict the peak share, \widehat{P}_{iB} for each observation i in sample B. Then, we regressed P_{iB} on \widehat{P}_{iB} (i.e. $P_{iB} = \delta_0 + \delta_1 \widehat{P}_{iB} + v_i$) and we jointly tested that $\delta_0 = 0$ and $\delta_1 = 1$. We repeated the Copas tests 1000 times. We found that the test was successful in 70% of the simulations, that the average value of the residuals v_i (in the validation sample) between actual and predicted shares was 0.3 percentage points (95% confidence interval [CI]: -0.04 – 0.04) and the average value for δ_1 was 0.94 (95% CI: 0.64 – 1.19). Based on the results of the test, the model is expected to predict, on average, out of sample peak share, with an accuracy of ± 4 percentage points. We conclude that the evidence for having a too-complex model was not strong and, therefore, the results should be valid outside the sample to make an average forecast prediction.

4. Alternative model based on revenue

We re-estimated the model replacing promotional spending with the ratio of total company revenue to total revenue of competing companies in the year prior to product launch (Table S3). We used revenue from the calendar year before drug launch so that revenue would not be affected by the performance of the drug in question. This approach has two advantages. First, the approach further mitigates concerns about the endogeneity of promotional spending, because promotional spending is replaced with firm revenue in the previous year. Second, this approach is easier for an analyst that might not have promotional spending data, but does have company revenue data that are readily available in company reports.

Financial analysts can use the model in at least two ways. First, they can use company revenue data as described above and apply them to the analysis in Table S3. Second, they can make assumptions on the promotional spending using analog products from Table S2.

References in the Appendix

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Table S1 | Brand name (with generic in parentheses) drugs included in the sample

Abilify (Aripiprazole)	Maxalt (Rizatriptan)	Zomig (Zolmitriptan)
Aciphex (Rabeprazole)	Metadate CD+Adderall XR (Methylphenidate + amphetamine and dextroamphetamine)	Zyprexa (Olanzapine)
Actonel (Risedronate)		Zyrtec (Cetirizine)
Actos (Pioglitazone)		
Allegra (Fexofenadine)	Nasonex (Mometasone furoate monohydrate)	
Allegra-D (Fexofenadine and pseudoephedrine)	Novolog (Insulin aspart)	
Aromasin (Exemestane)	Onglyza (Saxagliptin)	
Astelin (Azelastine)	Paxil (Paroxetine)	
Atacand (Candesartan)	Pravachol (Pravastatin)	
Avapro (Irbesartan)	Prevacid (Lansoprazole)	
Avodart (Dutasteride)	Prinivil (Lisinopril)	
Axert (Almotriptan)	Protonix (Pantoprazole)	
Azor (Amlodipine and olmesartan)	Razadyne (Galantamine)	
Boniva (Ibandronate)	Requip (Ropinirole)	
Cialis +Levitra (Tadalafil + vardenafil)	Reyataz (Atazanavir)	
Detrol+LA (Tolterodine)	Rhinocort Aqua (Budesonide)	
Diovan (Valsartan)	Ritalin-LA (Methylphenidate)	
Dulera (Formoterol and mometasone)	Seroquel (Quetiapine)	
Effexor+XR (Venlafaxine)	Starlix (Nateglinide)	
Enablex (Darifenacin)	Symbicort (Budesonide and formoterol)	
Exelon (Rivastigmine)	Tasigna (Nilotinib)	
Femara (Letrozole)	Vesicare (Solifenacin)	
Foradil (Formoterol)	Vioxx (Rofecoxib)	
Lescol (Fluvastatin)	Zoloft (Sertraline)	
Levemir (Insulin detemir)		

Table S2 | Summary statistics

All products (N=50)	Year of launch	Time-to-market (quarters)	Peak market share (%)	Share of promotional spending at launch (%)
Mean	2000	8.5	27	42
SD	4.6	5.1	14	18
Min	1988	0.0	2	7
Max	2010	14.0	52	91
Second entrants (N=29)	Year of launch	Time-to-market (quarters)	Peak market share (%)	Share of promotional spending at launch (%)
Mean	2000	9.7	36	53
SD	4.9	5.1	11	14
Min	1988	0.0	17	37
Max	2009	14.0	52	91
Third entrants (N=13)	Year of launch	Time-to-market (quarters)	Peak market share (%)	Share of promotional spending at launch (%)
Mean	2000	7.4	17	29
SD	4.4	4.8	6	10
Min	1993	2.3	8	15
Max	2010	14.0	25	47
Fourth entrants (N=8)	Year of launch	Time-to-market (quarters)	Peak market share (%)	Share of promotional spending at launch (%)
Mean	1999	6.0	12	24
SD	3.9	5.0	6	11
Min	1994	0.3	2	7
Max	2005	14.0	18	37

Table S3 | Regression results. The dependent variable is peak market share.

	Base case model with promotional expenses (standard error)	Model with company revenue ratio* (standard error)
Share of promotional spend (first 12 months)	0.459*** (-0.057)	
Time-to-market (“time”)	-0.009*** (-0.002)	-0.009** (-0.003)
Third entrant	-0.181*** (-0.036)	-0.248*** (-0.054)
Fourth entrant	-0.227*** (-0.04)	-0.331*** (-0.059)
Time x third entrant	0.007 (-0.004)	0.004 (-0.005)
Time x fourth entrant	0.010* (-0.004)	0.009 (-0.007)
Impact of third entrant launch on second entrant share	-0.063** (-0.019)	-0.039 (-0.03)
New entrant vs competition revenue ratio before launch		0.023 (-0.014)
Constant	0.232*** (-0.038)	0.442*** (-0.04)
Observations	50	50
R^2	0.887	0.733
Adjusted R^2	0.868	0.688

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

*Revenue ratio of new entrant relative to the competition is calculated the calendar year before launch

Table S4 | Regression results. Base case and two-stage least squares.

	Base case (standard error)	2SLS (standard error)
Share of promotional spend (first 12 months)	0.459*** (0.057)	0.419*** (0.085)
Time-to-market ("time")	-0.009*** (0.002)	-0.009*** (0.002)
Third entrant	-0.181*** (0.036)	-0.189*** (0.032)
Fourth entrant	-0.227*** (0.040)	-0.239*** (0.037)
Time x third entrant	0.007 (0.004)	0.007* (0.003)
Time x fourth entrant	0.010* (0.004)	0.010*** (0.003)
Second entrant x new competition	-0.063** (0.019)	-0.062** (0.020)
Constant	0.232*** (0.038)	0.254*** (0.051)
Observations	50	50

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

2SLS: two-stage least-square regression with instrumented share of promotional expenses

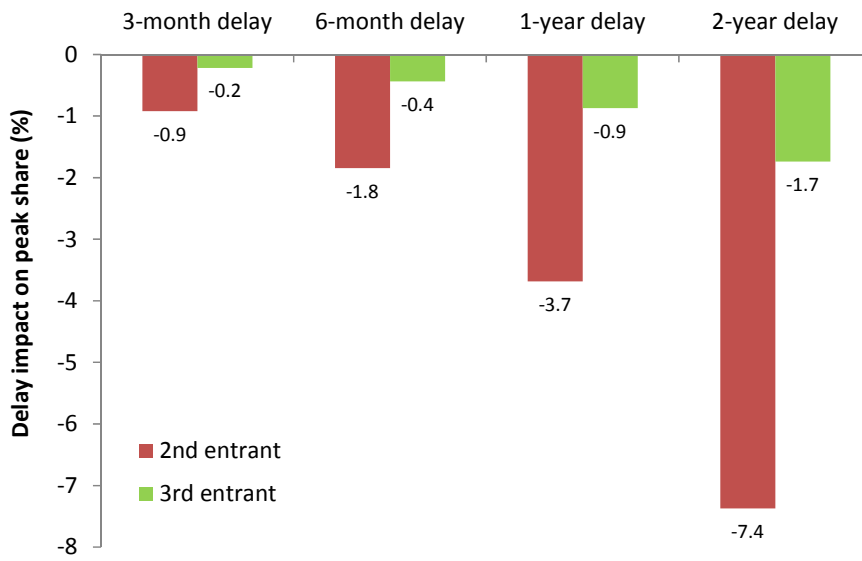


Figure S1 | Impact of a delay on peak market share potential.

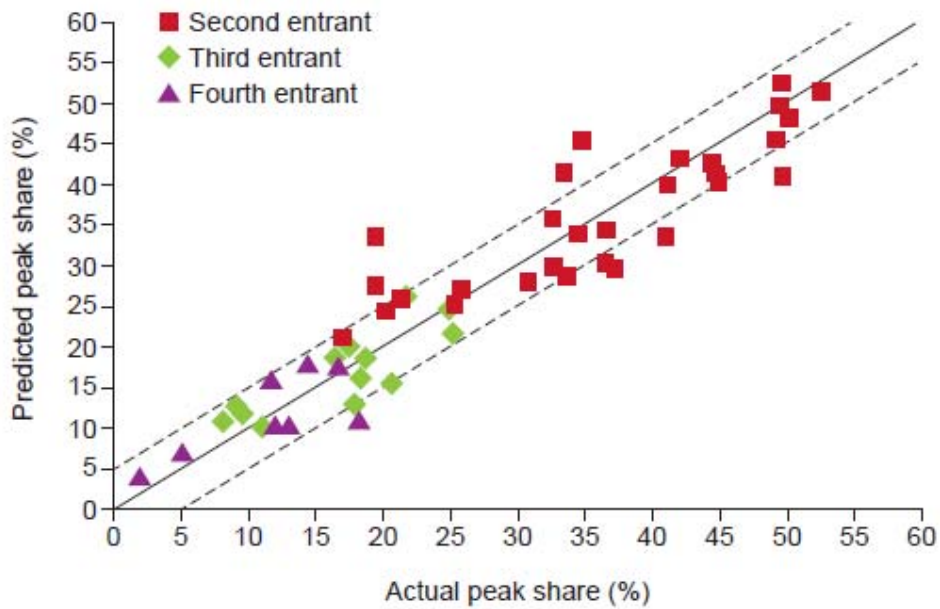


Figure S2 | Comparison between predicted and actual shares. Note: predicted and actual peak shares are equal for points lying on the solid lines. Predicted and actual peak shares differ by 5 percentage points for points on the dotted lines.