

Impact of Withdrawal of Field-Based Promotion for Kadian

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Background and Objectives

Background:

- Actavis Pharmaceuticals recently acquired Kadian, an extended release morphine sulfate product, from King Pharmaceuticals. The management of Actavis seeks to understand the impact of discontinuing field-based promotion for Kadian and has retained Health Products Research to conduct the required analysis.

Objectives:

- Develop historic promotion response curves for Kadian and estimate the impact of withdrawing field-based promotion on Kadian's Rx volume based on these curves
- Estimate the impact of withdrawing field-based promotion on generation of new patients.
- Develop a profile of existing patients and build a framework for further investigation of the effect of various marketing programs on the retention of existing patients
- Develop a basic patient longitudinal-based forecasting/simulation tool

Executive Summary: Overall Results

- Utilizing physician-level prescribing data, the impact of reduction in detailing from the 2008 levels was assessed for four scenarios and three ranges (optimistic/baseline/pessimistic)*.

A

**Complete “Pull Back” From
2008 Level**

39/ 47/ 53% drop in TRxs in 2009
compared to the historical volume of 701K.

B

Reduce Detailing: 75%

30/ 36/ 43% drop in TRxs in 2009
compared to the historical volume of 701K.

C

Reduce Detailing: 50%

16/ 22/ 27% drop in TRxs in 2009
compared to the historical volume of 701K.

D

Reduce Detailing: 25%

5/ 9/ 14% drop in TRxs in 2009
compared to the historical volume of 701K.

- Utilizing patient-level data, the impact of a reduction in detailing from 2008 levels was assessed for one scenario.

A

**Complete “Pull Back” From
2008 Level**

30/ 34/ 39% drop in Net Sales Dollars in
2009 compared to \$181MM level in 2008.

- So net/net, we expect a reduction of 34-47% of Kadian TRx's (and \$'s) in 2009 as a result of withdrawing detailing.

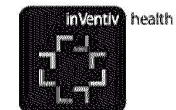
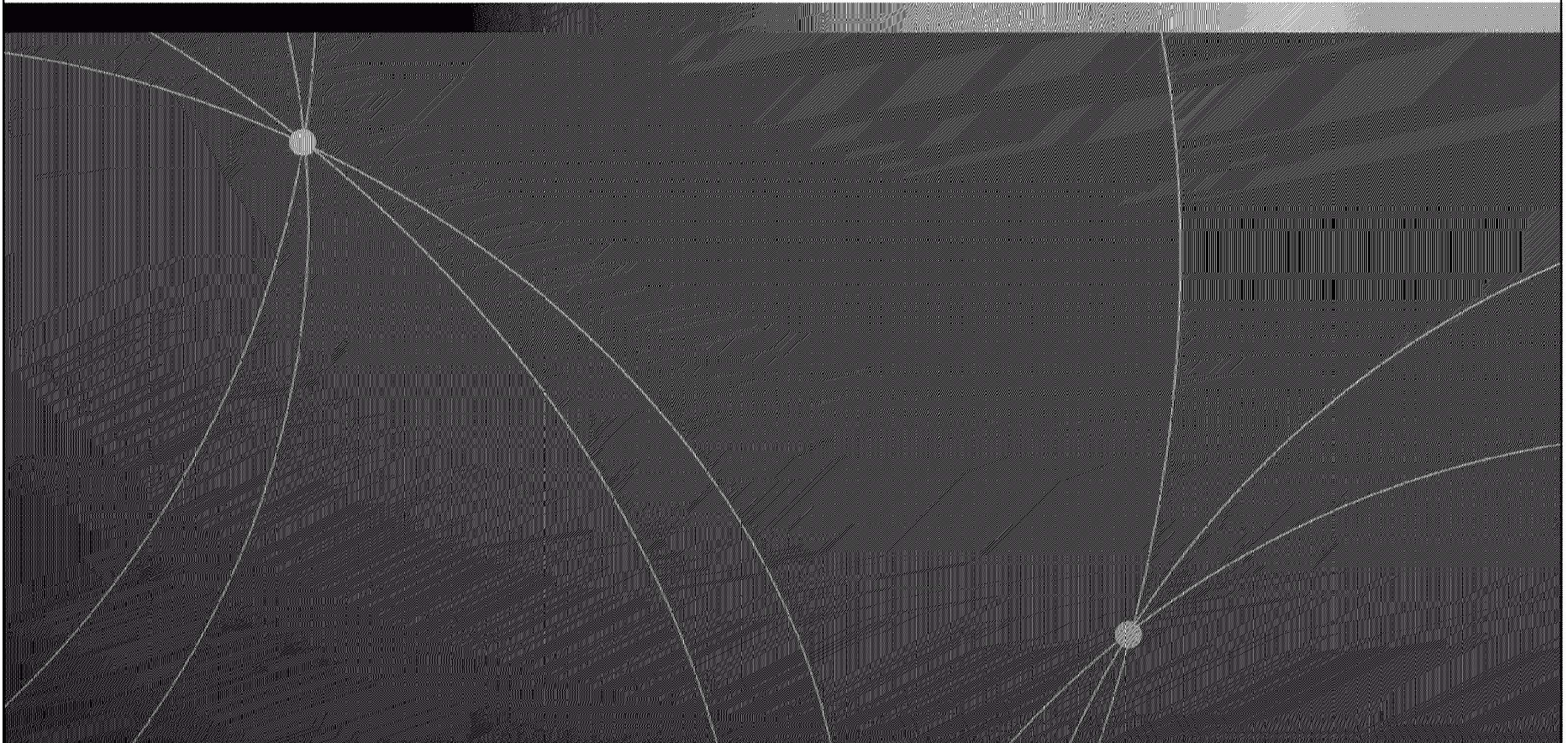


* HPR did not attempt to “optimize” the reductions, and detailing was reduced across the board for each segment modeled.



3

Impact of Withdrawal of Field-Based Promotion: Rx Data Based Approach



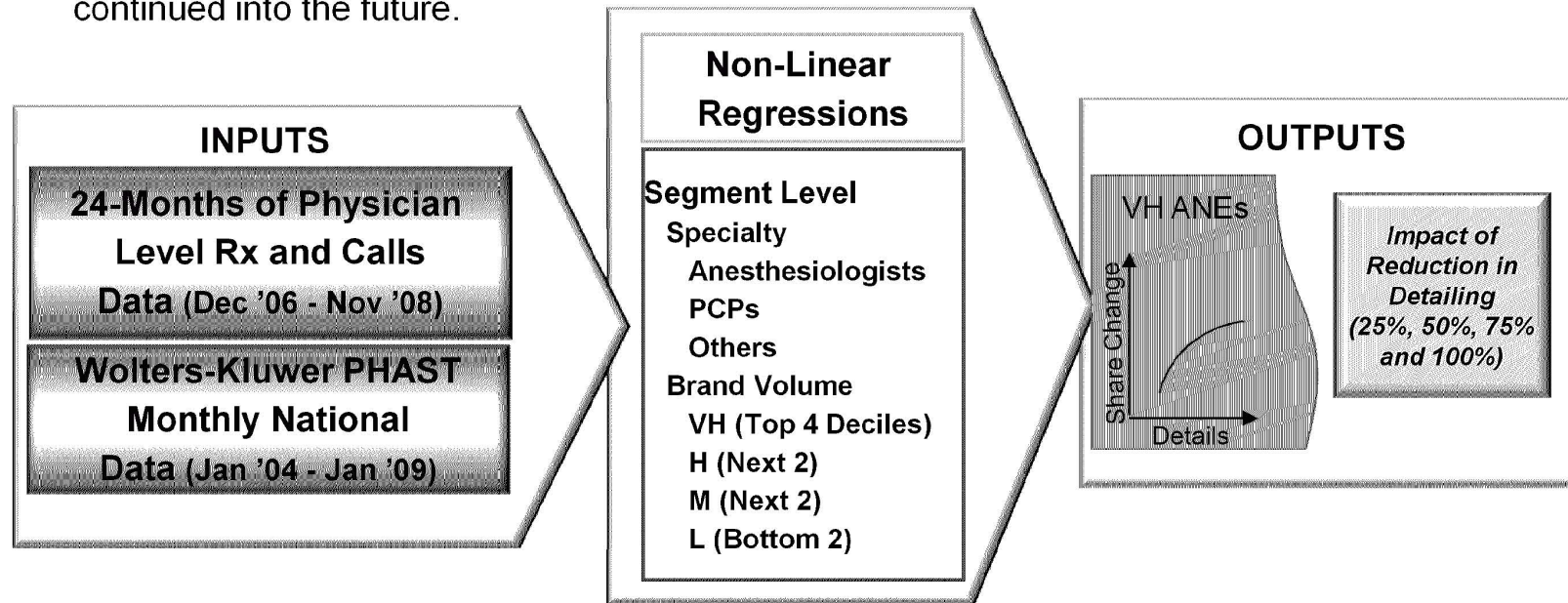
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Data and Methodology

- The PROM model uses non-linear regressions to quantify the relationship between change in product share and its detailing activity. These models have been developed for combinations of physician segments based on specialty and class volume.
- Analysis was done separately for two sub-periods within the 24-month horizon for which data were available (e.g., 2007 and 2008).
 - Results obtained using 2007 data are presented here because the detailing data for 2008 was incomplete*.
 - Detailed physicians were included in the statistical model and the results were used to project the impact of zero detailing.
 - For the non-detailed physicians the observed historical trend in their TRx volume was continued into the future.



Long Acting Opioids (LAO) Market Definition and Data Sources

- The following definition for the LAO market is used.

- *Kadian*
- *Oxycontin**
- *Oxycodone HCL**
- *MS Contin*
- *Morphine Sulfate**

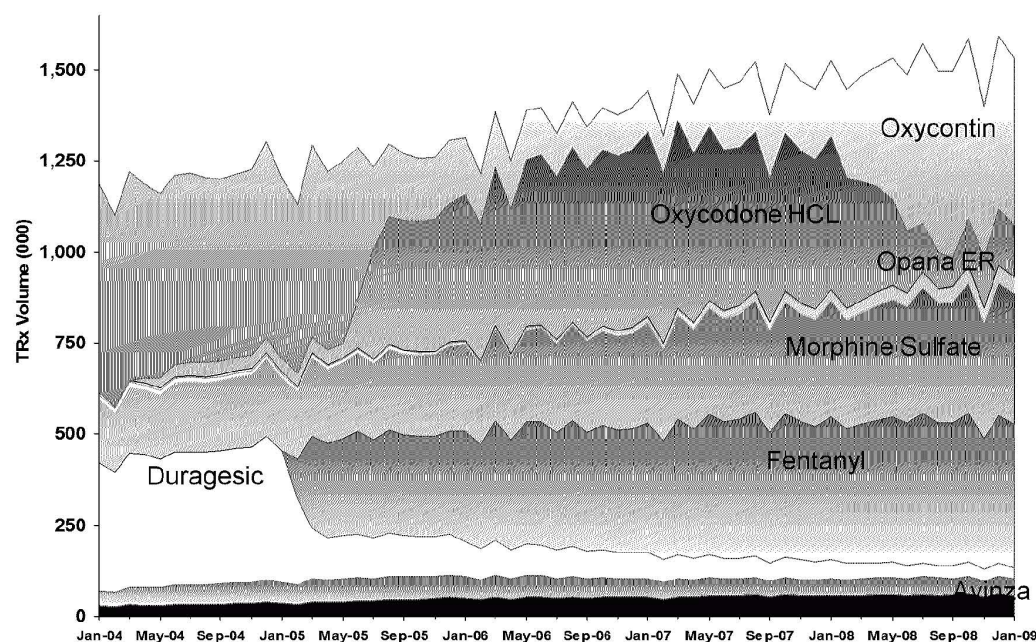
- *Fentanyl*
- *Duragesic*
- *Oramorph*
- *Avinza*
- *Opana ER*

Data Sources:

- IMS Xponent market Rx data for Kadian for December 2006 – November 2008.
- Alharma calls data for December 2006 – November 2008: Note that for 2008, this data only indicated if an Alharma rep delivered a call to a physician. The information did not specify if a Flector and/or Kadian detail was delivered.
- Wolters Kluwer PHAST Monthly Rx data for a 61-month period ending January 2009: This dataset is used for profiling the market and calculating Kadian's market share only.

LAO Market: 5-Year Monthly TRx Volume Trend

- The market (6% CAGR '04-'09), as well as Kadian (16% CARG '04-'09) TRxs, show a long term growth pattern.
- Kadian exhibits an inconsistent growth pattern at the end of the year. Some years equaling market rates (12/04-1/05, 12/07-1/08), some years lagging market rates (12/05-1/06, 12/06-1/07 & 12/08-1/09). Most recently the disparity appears to be increasing.
- Finally, the market has experienced numerous product launches, withdrawals and reintroduction which may contribute to overall market churn.



End of Year Growth Rates

	Kadian	Market
Dec 04 - Jan 05	-7.6%	-7.6%
Dec 05 - Jan 06	-2.7%	0.6%
Dec 06 - Jan 07	1.1%	3.4%
Dec 07 - Jan 08	5.1%	5.5%
Dec 09 - Jan 09	-9.6%	-3.7%



Source: Wolter's Kluwer PHAST monthly Rx data for January 2004 – January 2009
Oramorph SR and MS Contin have small TRx volumes and could not be shown on the chart.



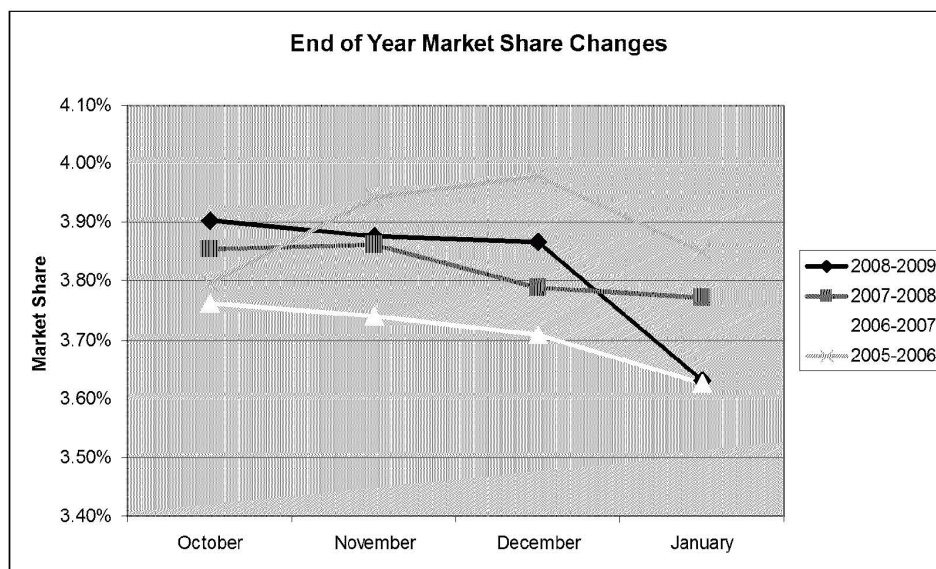
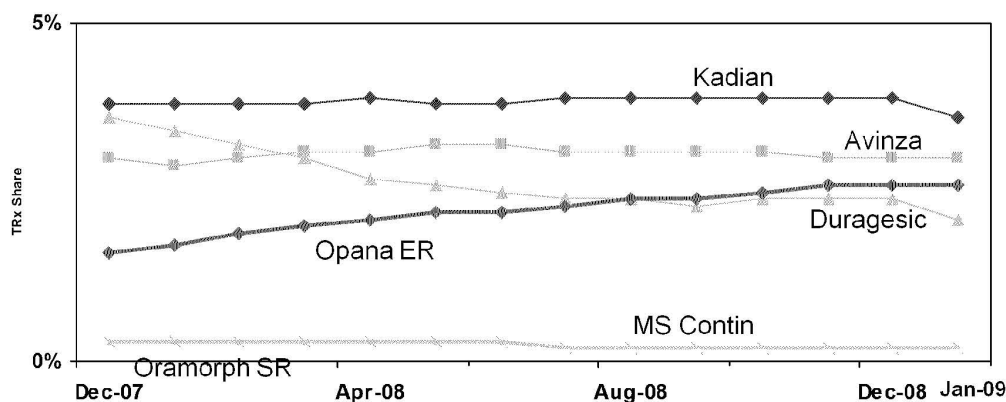
LAO Market: 1-Month and 1-Year Changes in TRx Volumes

- The TRx volume for the LAO class has declined by -3.7% from Dec '08 to Jan '09. Every product in the class experienced a decline in the TRx volume for this period. However, the month over month drop in Kadian's TRx volume has been more pronounced (at -9.6%) than the class (-3.7%) and every for every other competitor except Duragesic (-14.1%).
- When Jan '09 TRxs are compared against those for Jan '08, again, a larger drop is seen for Kadian (-3.3%) than its key branded competitors except Duragesic (-37.5%). The market volume rose from Jan '08 to Jan '09 by 0.5%.

Growth Rate: Jan 2009 from ...

	Dec 2008	Jan 2008
Avinza	-4.8%	1.5%
Duragesic	-14.1%	-37.5%
Fentanly	-2.7%	-0.2%
Kadian	-9.6%	-3.3%
Morphine Sulfate	-1.5%	13.9%
MS Contin	-6.1%	-14.7%
Opana ER	-1.9%	56.2%
Oramorph SR	-2.9%	0.4%
Oxycodone HCL	-8.1%	-66.2%
Oxycontin	-3.2%	120.0%
Class	-3.7%	0.5%

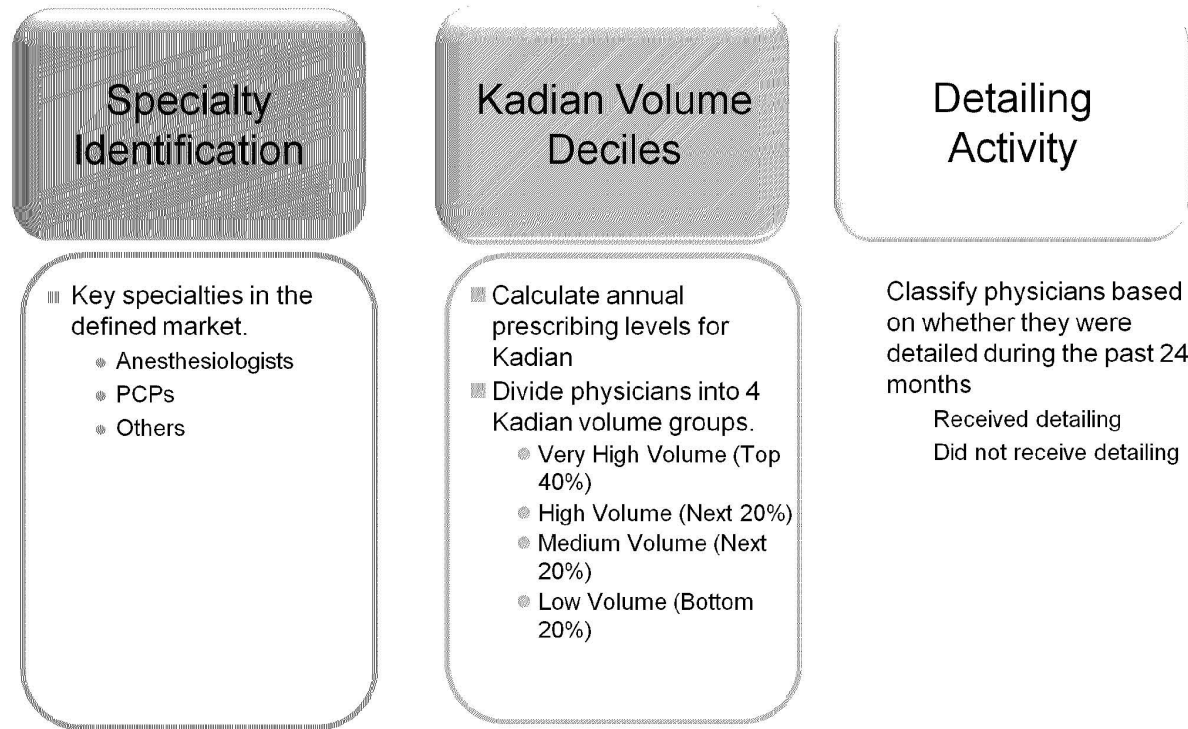
LAO Market: Monthly TRx Share Trend



- Kadian's market share was 3.6% during Jan '09. This was a decline of -0.25% from Dec '08 and of -0.1% from Jan '08.
- But for Duragesic these declines are the most severe among the branded competitors.
- Kadian's typically appears to lose market share at year end.
- However, during the most recent year-end, Kadian's market share decline was the most pronounced.

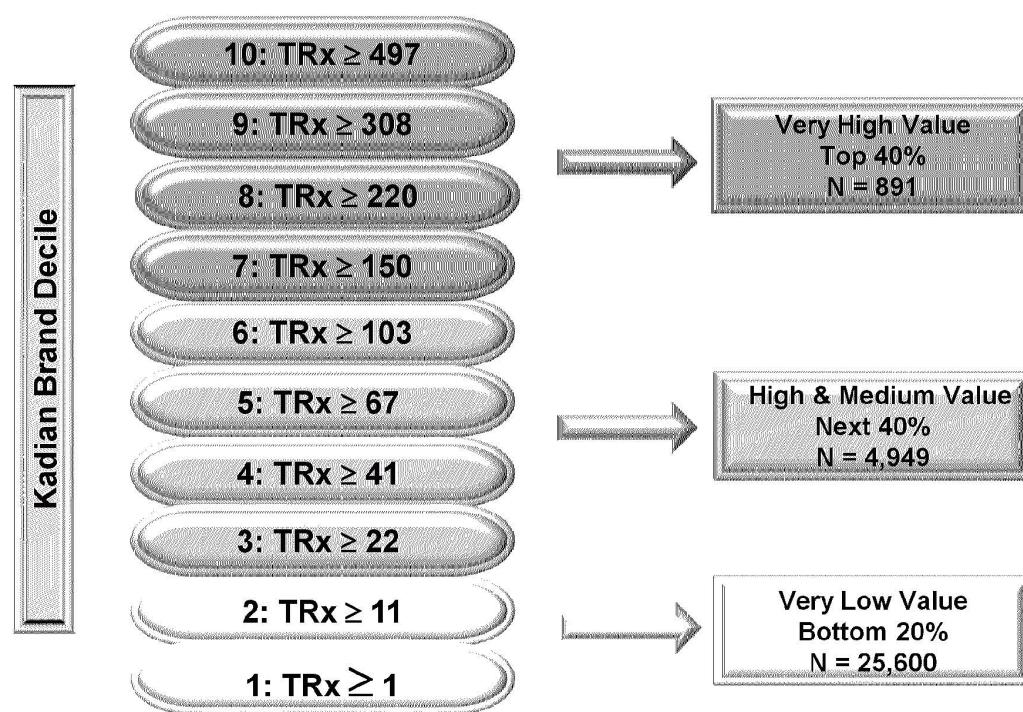
Market Segmentation

- The complete segmentation solution incorporates two dimensions:



Physician Value: Deciles Based on Brand TRx Volume During 2007*

- After it was decided that the impact of reduced detailing should be assessed based on data for 2007, HPR reconstructed deciles using prescribing data across all physicians in the universe for 2007. These were further aggregated into 3 categories.
- Deciles developed using data for the most recent 12 months had similar cut-off points and are in the appendix.



Based on IMS Xponent data from December 2006 – November 2008. A total of 31,440 physicians write Kadian during December 2006 thru November 2007. Only these doctors are included in this analysis.

* Actual data period is from Dec '06 through Nov '07

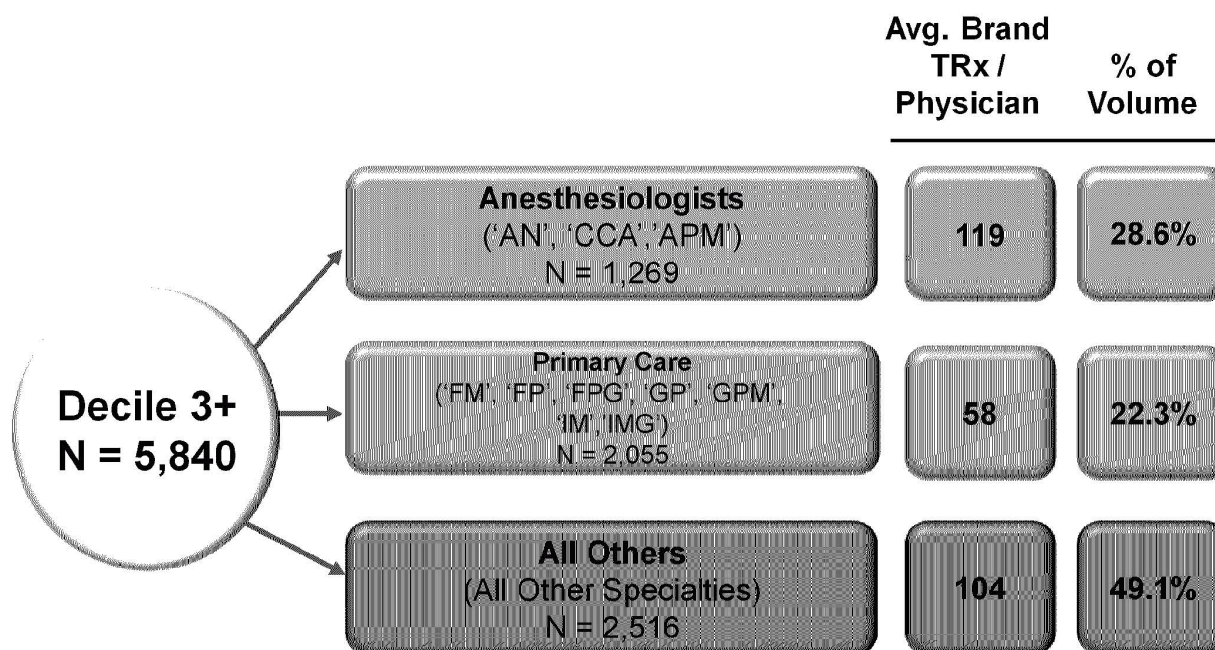


11

Kadian Specialty Aggregation

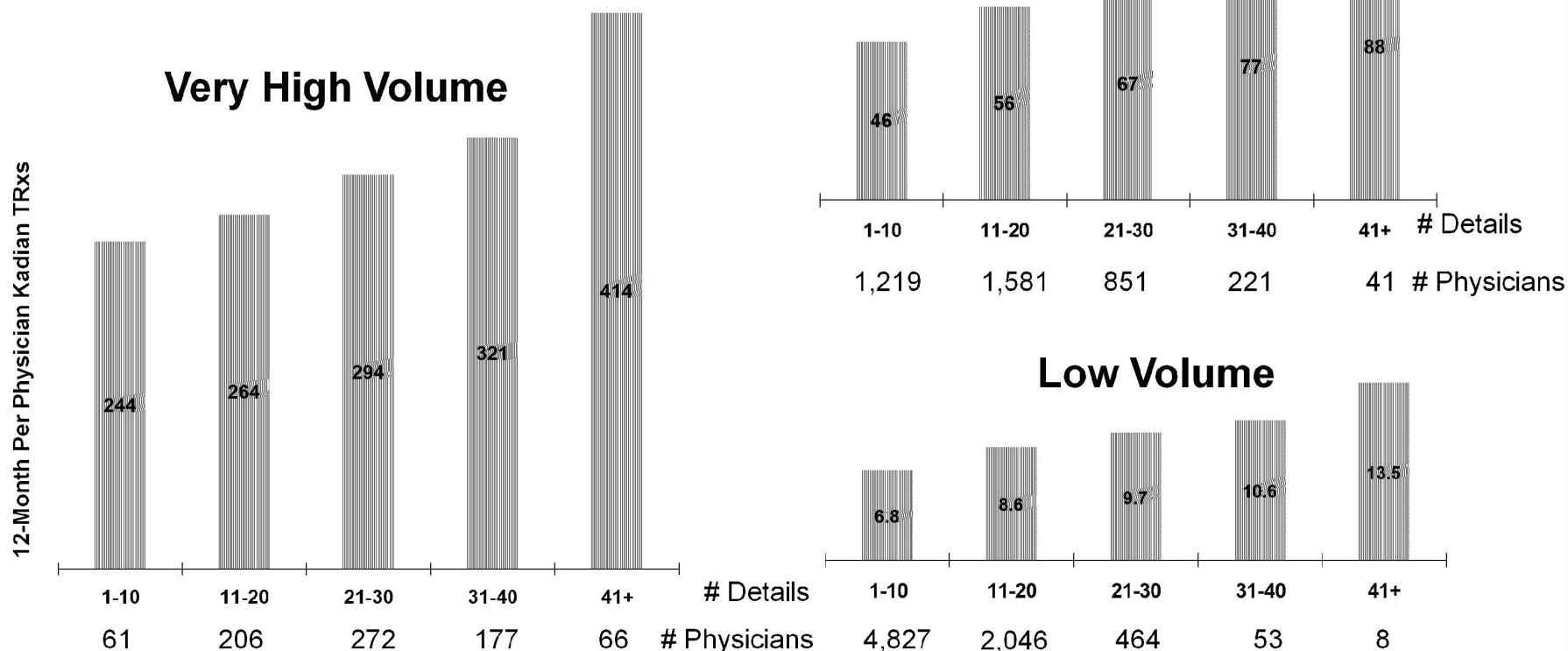
Deciles 3+ Physicians During 2007*

- The average TRx volume per physician is the highest at 119 for anesthesiologists and only 58 for PCPs.
- Anesthesiologists account for 28.6% of the Kadian TRx volume with 22% of the physicians.



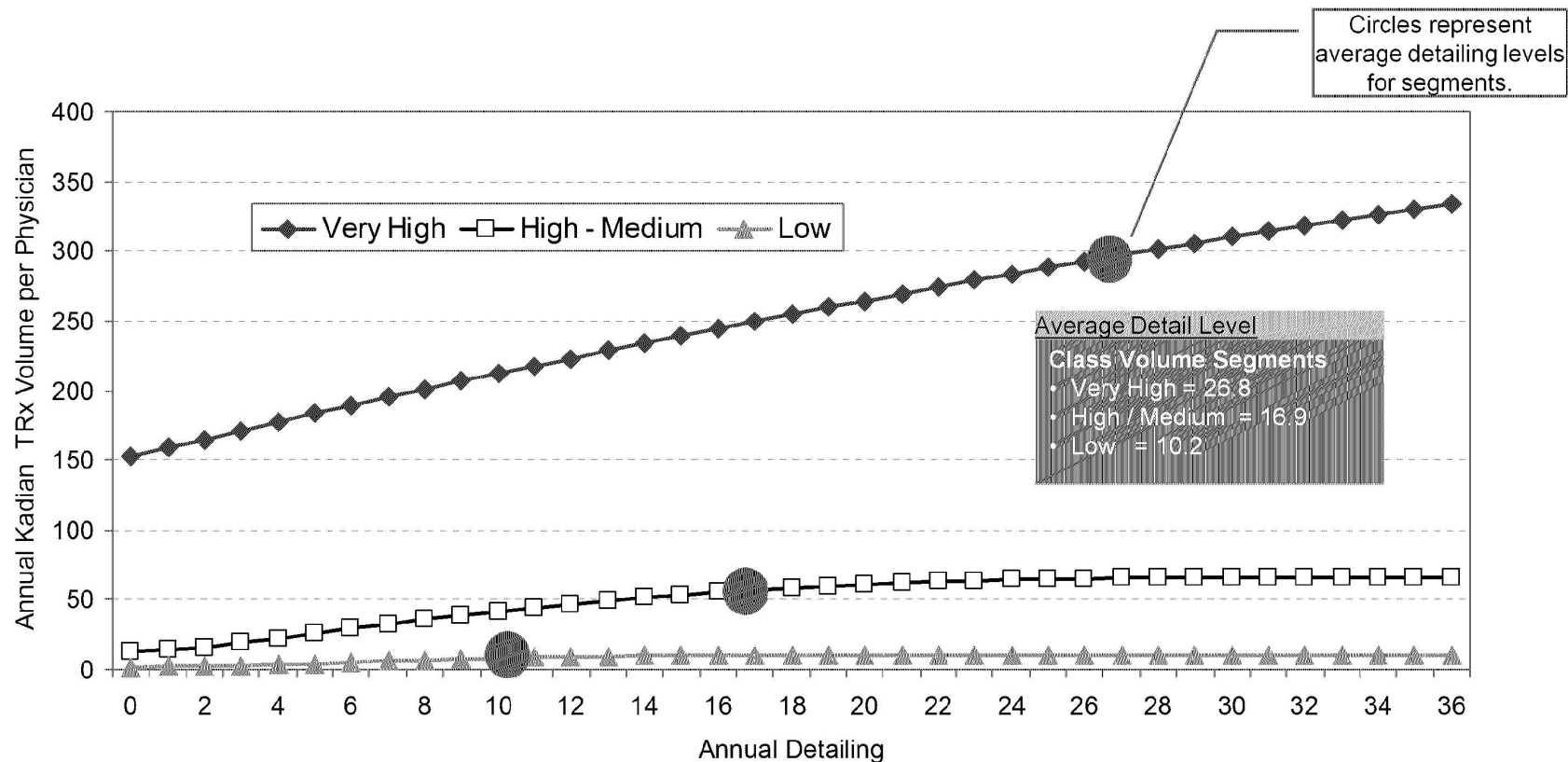
TRxs For Kadian Volume Segments During 2007* By Number of Details During 2007

- The TRx volume increased with increase in annual detailing volume for each segment of physicians.



Promotion Response for Physicians

- Promotion response curves were developed separately for the Very High, High / Medium and Low volume Kadian segments.
 - Since the responsiveness of the physicians in the volume segments were similar for the three specialties, it was decided not to separate out physicians by specialty.



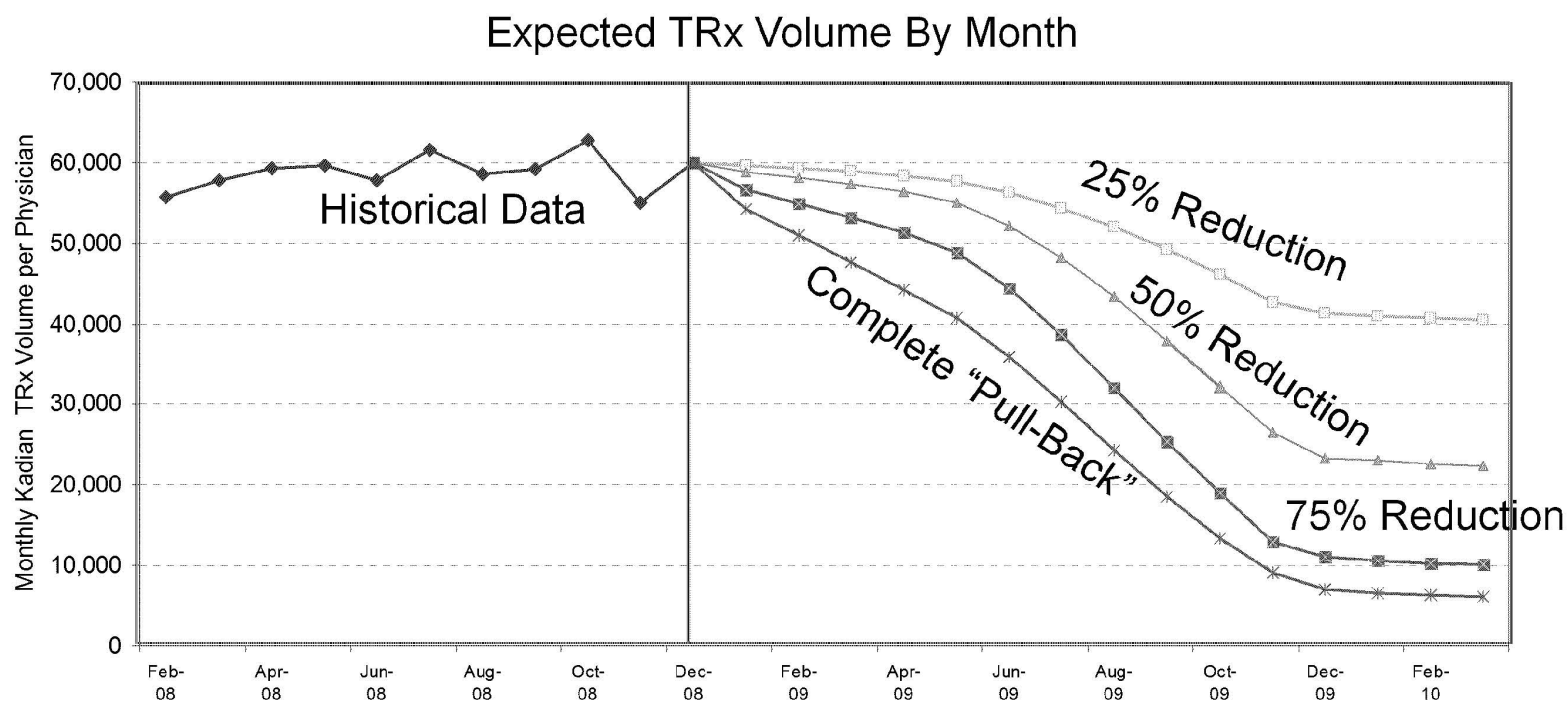
Scenarios – We Looked at Four Scenarios

- In order to assess the impact of pulling back on field based promotion we looked at four scenarios that focused on across the board reductions in detailing.
- The average detailing level for each physician segment was reduced by set percentages across the board and no attempt was made to allocate the available calls in an optimal manner.

A	Complete “Pull Back”	Reduce the average number of calls to 0 for every physician
B	Reduce Detailing: 25%	Reduce the average number of calls by 25% for every physician segment
C	Reduce Detailing: 50%	Reduce the average number of calls by 50% for every physician segment
D	Reduce Detailing: 75%	Reduce the average number of calls by 75% for every physician segment

Impact of Reduced Detailing on Kadian TRx Volume Over Time

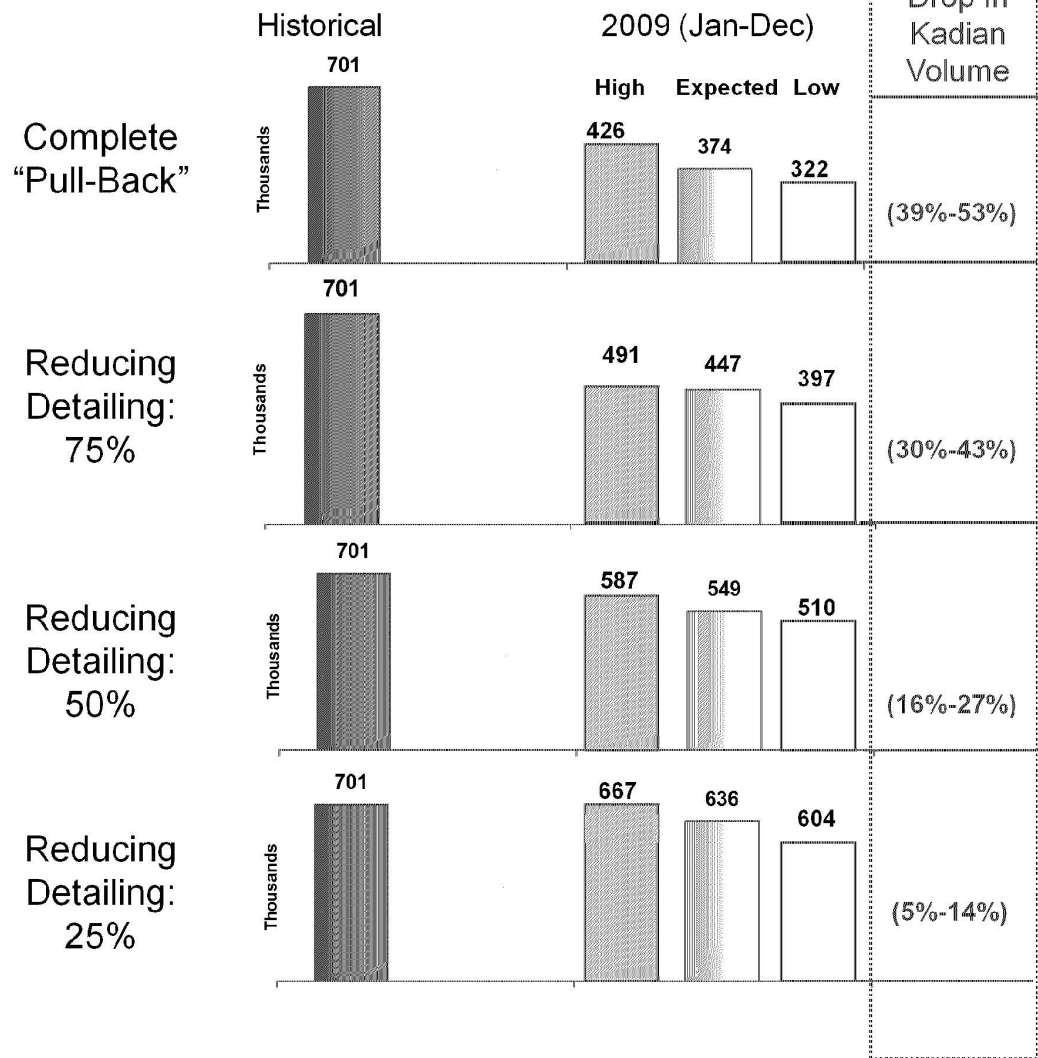
- The impact of the reduction in detailing volume over time is expected to be “inverse S-shaped”, i.e., the decline is relatively slow in the beginning, picks up momentum as months pass by and then starts to stabilize.



Impact of Reduced Detailing on Kadian TRx Volume (2009)

- HPR's analysis shows that the impact of reducing detailing could be substantial.
- If detailing is completely withdrawn in 2009, Kadian is expected to lose close to 50% of its TRx volume compared to the 701K TRxs in 2008.
- The expected losses in TRxs are 36%, 22% and 9% under the 75%, 50% and 25% detailing reduction scenario respectively.
- However, these reductions in details assume naïve, across the board, reductions. Therefore, a more strategic approach to reducing (or adding) details would yield improved results.

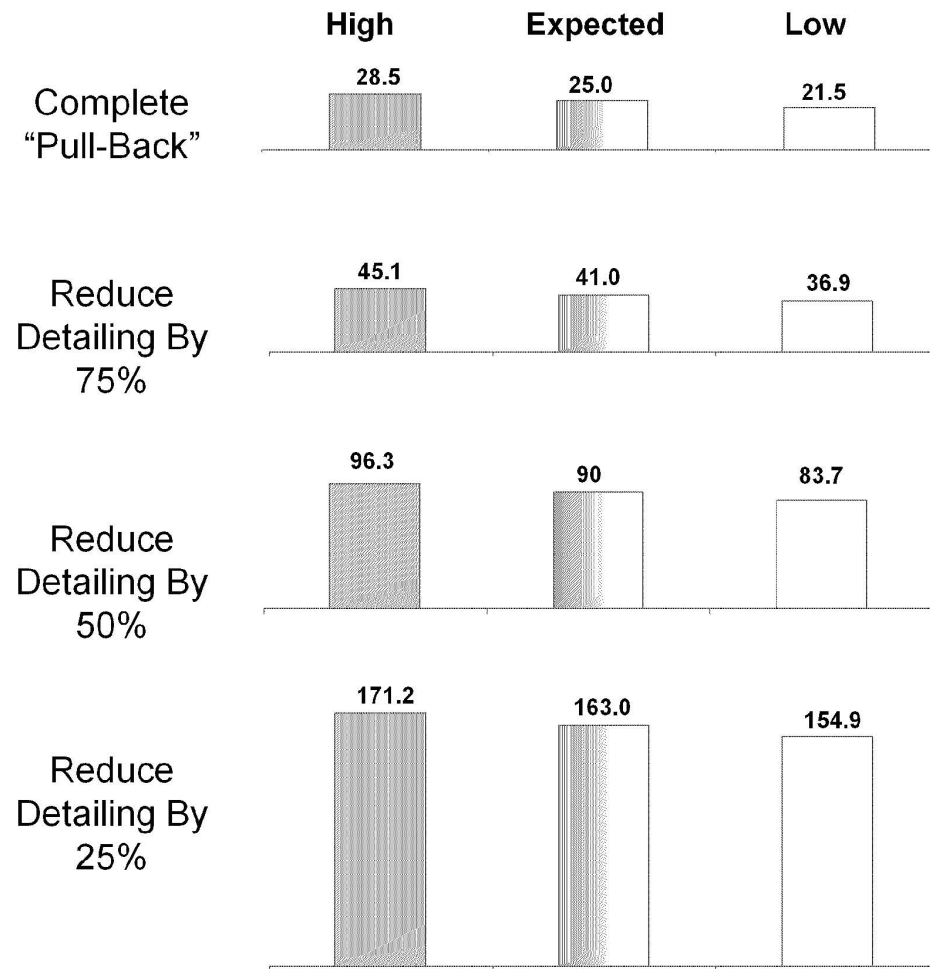
Estimated TRx Volumes ('000's)



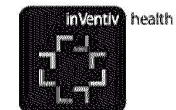
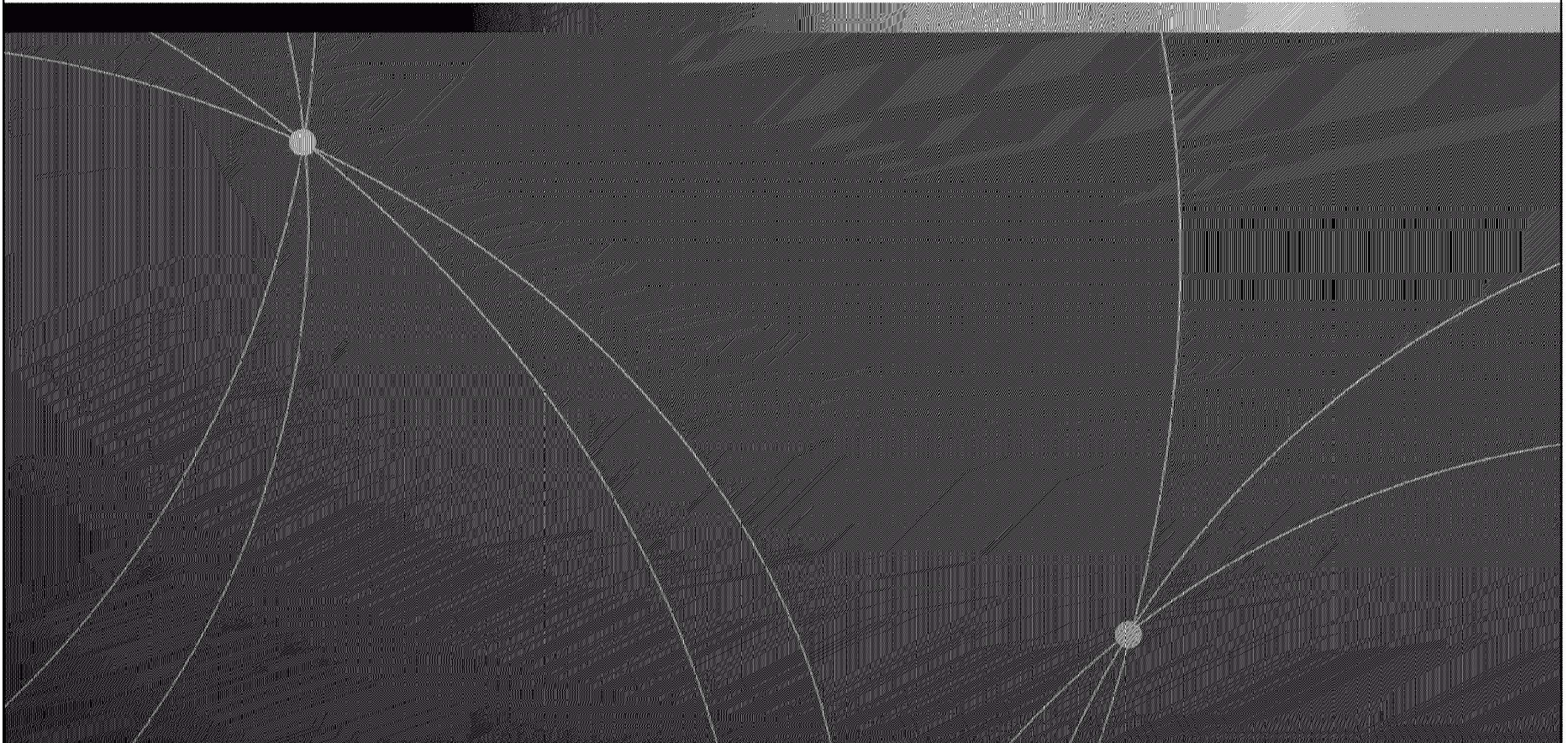
Impact of Reduced Detailing on Kadian TRx Volume (Jan-Apr 2010)

- Expected monthly TRx volumes during the first four months of 2010 are stable but at a reduced level.
- In other words, we estimate that most of the volume loss due to withdrawal of detailing will occur in 2009.
- Again, the reductions in details assume naïve, across the board, cuts. Therefore, a more strategic approach to reducing (or adding) details would yield improved results.

Estimated TRx Volumes for Jan-Apr 2010 ('000's)



Impact of Withdrawal of Field-Based Promotion: Patient-Based Approach



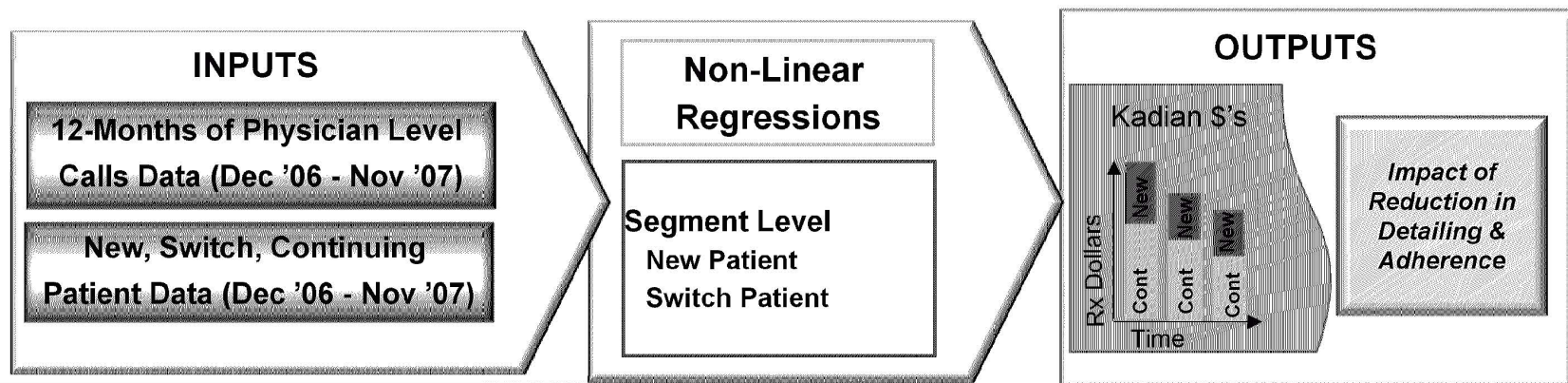
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Data and Methodology

- Utilizing Adheris' patient longitudinal database we estimate the number of new, switch and continuing patients for Kadian in 2008
 - New patients are defined as naïve to Kadian in the prior 12-months
 - Switch patients are defined as utilizing a competitive product in the prior 12-months
 - Continuing patients are defined as utilizing at least one Kadian Rx in the prior 12-months
- Expected patient values are calculated for new, switch and continuing patients
- As the Adheris database does not capture every patient in the category, we project Adheris' patient Rx volumes to the universe of Kadian users
- Statistical analysis was then performed to determine the relationship between Kadian details and new & switch patient volumes
- A financial model was developed to calculate the future expected dollars associated with the withdrawal of detailing and different adherence assumptions

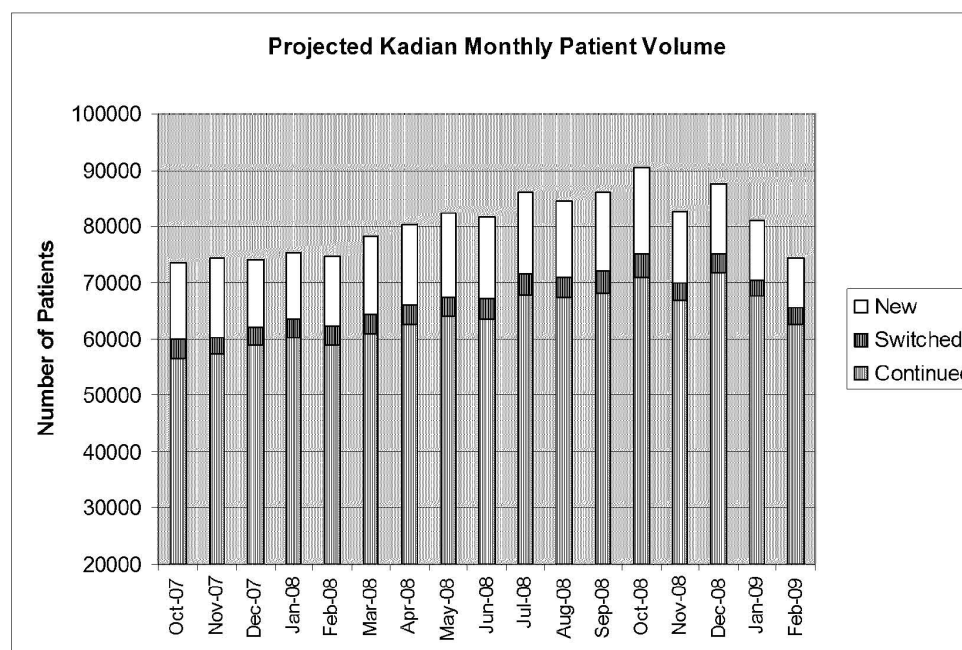


Summary of Patient Data Statistics

- Utilizing Adheris' patient longitudinal database we estimate the number of new, switch and continuing patients for Kadian in 2008
 - New patients are defined as naïve to Kadian in the prior 12-months
 - Switch patients are defined as utilizing a competitive product in the prior 12-months
 - Continuing patients are defined as utilizing at least one Kadian Rx in the prior 12-months

Projected Kadian Patients/Percentages from Adheris Database

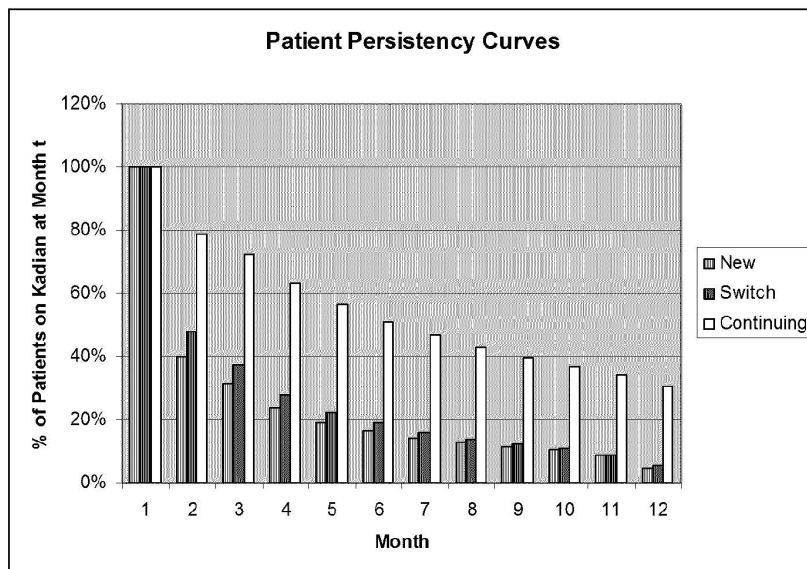
Month	New	Continued	Switched
Oct-07	13682 (19%)	56559	3430
Nov-07	14184 (19%)	57203	2912
Dec-07	12198 (16%)	58773	3054
Jan-08	12018 (16%)	60045	3415
Feb-08	12599 (17%)	58836	3273
Mar-08	13973 (18%)	60885	3509
Apr-08	14334 (18%)	62392	3627
May-08	15024 (18%)	64142	3321
Jun-08	14334 (18%)	63412	3831
Jul-08	14522 (17%)	68012	3509
Aug-08	13596 (16%)	67329	3603
Sep-08	13925 (16%)	68060	3956
Oct-08	15276 (17%)	70964	4239
Nov-08	12536 (15%)	66819	3273
Dec-08	12560 (14%)	71851	3258
Jan-09	10479 (13%)	67761	2779
Feb-09	8854 (12%)	62565	3054



- Decreasing trends in patient volume over the latest three months are concerning

Calculation of Expected Patient Values

- To calculate future expected revenue by patient type we:
 - Estimate the expected future usage from patient persistency curves



Rx Fills per Year

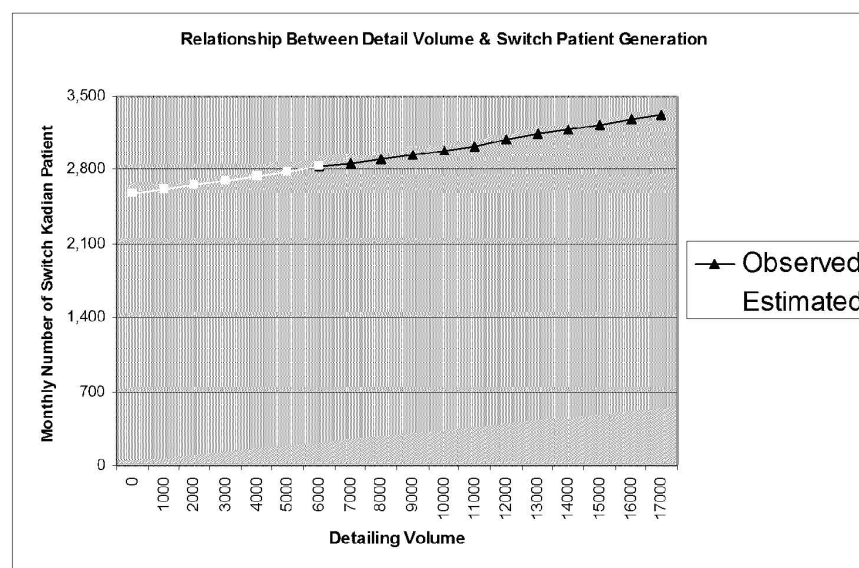
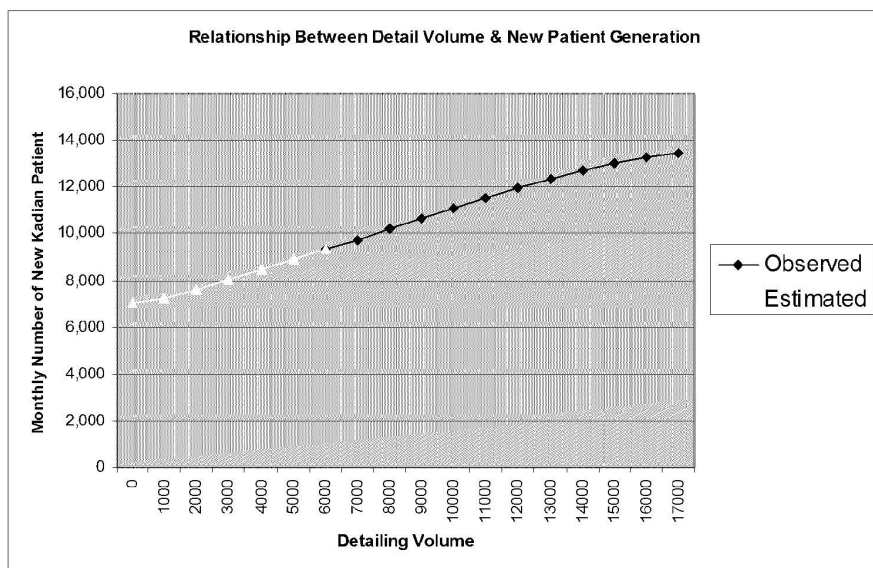
New	2.92
Switch	3.21
Continuing	6.51

- Estimate average Net Sales across dosage forms & fill sizes & combine the two estimates

Patient Type	Average Net Sales/Tablet	Tablets per Fill Rx	Patient Value (Net Sales) per Fill	Fills per Year	Patient Value (Net Sales) per Year
New	\$6.13	28.6	\$175.24	2.92	\$ 512
Switch	\$6.13	28.6	\$175.24	3.21	\$ 563
Continuing	\$6.13	28.6	\$175.24	6.51	\$ 1,141

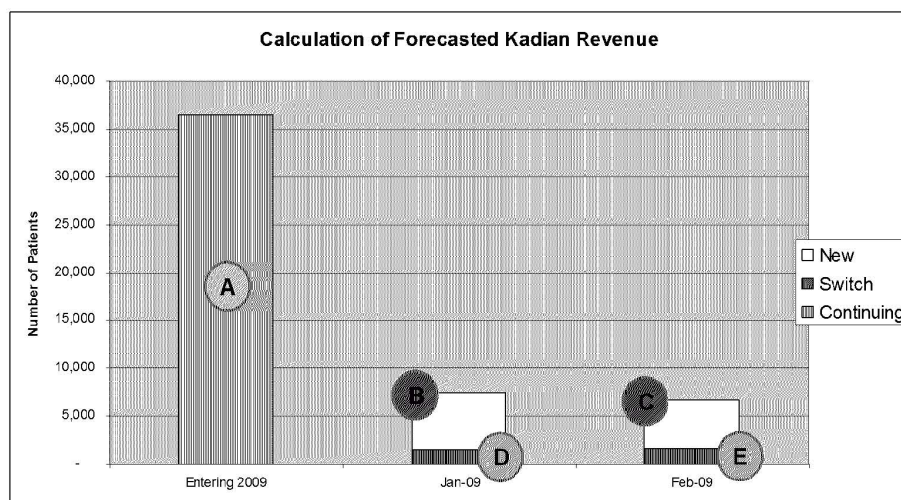
Effect of Detailing on New/Switch Patient Generation

- A statistical model was developed to estimate the relationship between detailing and new and switch patient generation.
- Our analysis suggests that:
 - Monthly new patient volume could decrease to a zero-detailing, steady-state volume of ~7065 new patients per month (a 42% reduction in the average trailing 6-month new patient generation rate)
 - Monthly switch patient volume could decrease to a zero-detailing, steady-state volume of ~2575 switch patients per month (a 25% reduction in the average trailing 6-month switch patient generation rate)



Financial Impact - Overview

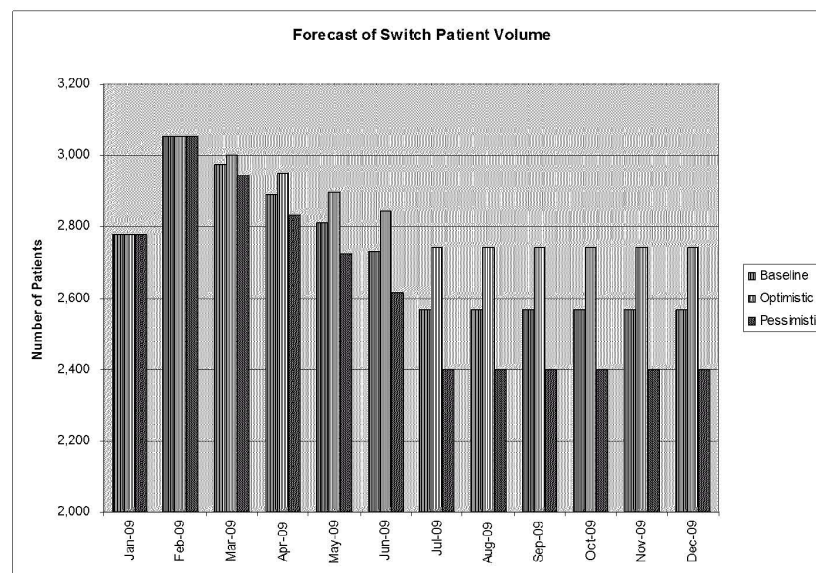
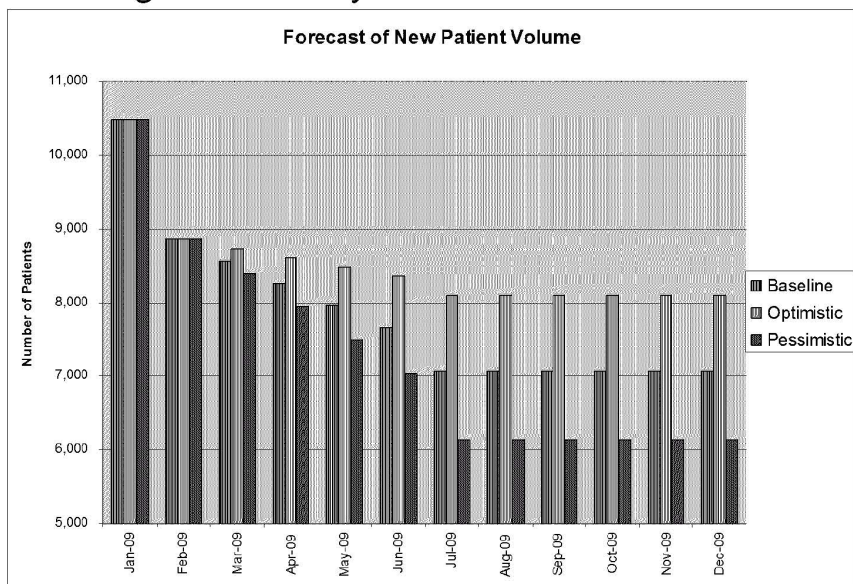
- We develop a financial template to model the impact of the withdrawal of detailing effort
- The general process is as follows:
 - Forecast new/switch patient volumes for 2009 & account for continuing patient volume
 - Recognize that as detailing is eliminated the “value” of a new, switch and continuing patient will decrease vis a vis when detailing was present
 - Calculate the revenue contribution, for each cohort of forecasted new, switch and continuing patients in 2009
 - Develop a optimistic, pessimistic, baseline forecast of revenue for 2009



	Value of Continuing Patients as of 1/1/09	Value of New Patients	Value of Switch Patients
As of 12/31/08	A		
+			
Jan 2009		B	D
+			
Feb 2009		C	E
+			
	
+			
Dec 2009			
Total	\$	\$	\$

Financial Impact – Patent Volume & Value Forecast

- Forecasts of new & switch patient volumes in the absence of detailing were developed noting that steady-state volumes will be reached six months post the withdrawal of detailing.



- We note that the expected value of new, switch and continuing patients should be decreased in the absence of detailing.
 - We have previously estimated that new patient volume, in the baseline scenario, will decrease by 42%.
 - This can also be thought of as a 42% decrease in the likelihood that a patient will receive Kadian each time a new patient presents to the physician
 - Continuing patients, however, are more likely to receive a Kadian Rx given their 2X patient value vis a vis new patients
 - Therefore, we will assume that forward looking patient values will be reduced by a factor that is one-half the expected decrease in new patient volume (ex. in the baseline case, a 42% reduction in new patient volume, translates to a 21% reduction in patient value)

Financial Impact - Summary

- For each assumption regarding: 1) New/Switch Patient Generation and 2) Reduction in Future Patient Value, we calculate revenue contribution by patient type

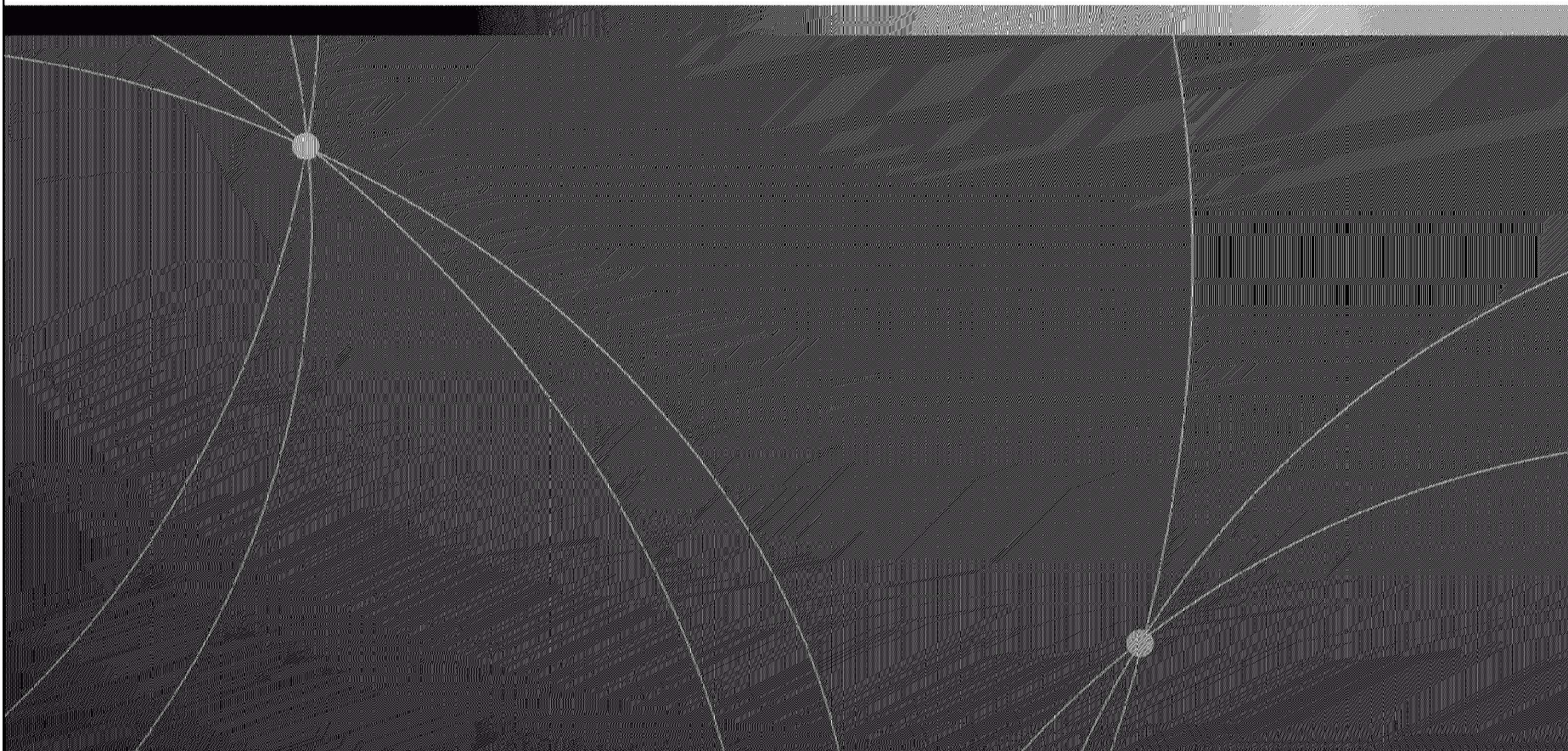
Patient-Based Impact of Removing Kadian Detailing: Calendar Year 2009

Patient Type	Optimistic Assumption		Baseline Assumption		Pessimistic Assumption	
	34% Reduction in New Patients 20% Reduction in Switch Patients 17% Reduction in Patient Value		42% Reduction in New Patients 25% Reduction in Switch Patients 21% Reduction in Patient Value		50% Reduction in New Patients 30% Reduction in Switch Patients 25% Reduction in Patient Value	
New	\$	33,581,379	\$	29,844,986	\$	26,527,066
Switch	\$	12,149,146	\$	11,183,079	\$	10,255,551
Continuing	\$	81,543,613	\$	77,613,800	\$	73,683,988
Total Forecasted Net Sales	\$	127,274,138	\$	118,641,865	\$	110,466,605
2008 Baseline Net Sales	\$	181,000,000	\$	181,000,000	\$	181,000,000
Change in Revenue	\$	(53,725,862)	\$	(62,358,135)	\$	(70,533,395)
% Reduction		30%		34%		39%

Patient-Based Impact of Removing Kadian Detailing: January 2010 - April 2010

Patient Type	Optimistic Assumption		Baseline Assumption		Pessimistic Assumption	
	34% Reduction in New Patients 20% Reduction in Switch Patients 17% Reduction in Patient Value		42% Reduction in New Patients 25% Reduction in Switch Patients 21% Reduction in Patient Value		50% Reduction in New Patients 30% Reduction in Switch Patients 25% Reduction in Patient Value	
New	\$	14,136,234	\$	11,868,179	\$	9,913,640
Switch	\$	5,286,249	\$	4,742,902	\$	4,228,779
Continuing	\$	14,210,777	\$	13,525,920	\$	12,841,063
Total Forecasted Net Sales	\$	33,633,260	\$	30,137,001	\$	26,983,482

Appendix



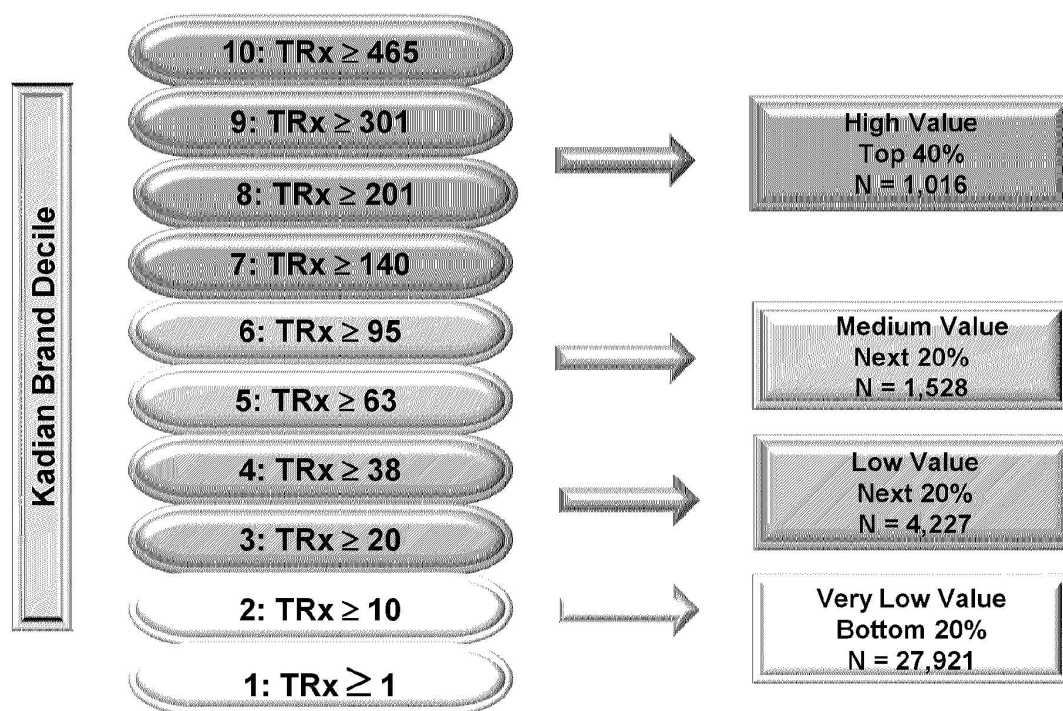
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Physician Value: Deciles Based on Brand TRx Volume During Most Recent 12-Months (Dec '07-Nov '08)

- Deciles are constructed using prescribing data across all physicians in the universe. These are further aggregated into 4 categories.



Based on IMS Xponent data for 48,321 physicians from December 2007 – November 2008.
13,629 physicians did not write any Kadian TRx during the most recent 12 months ending November 2008.
They are not included in this analysis.

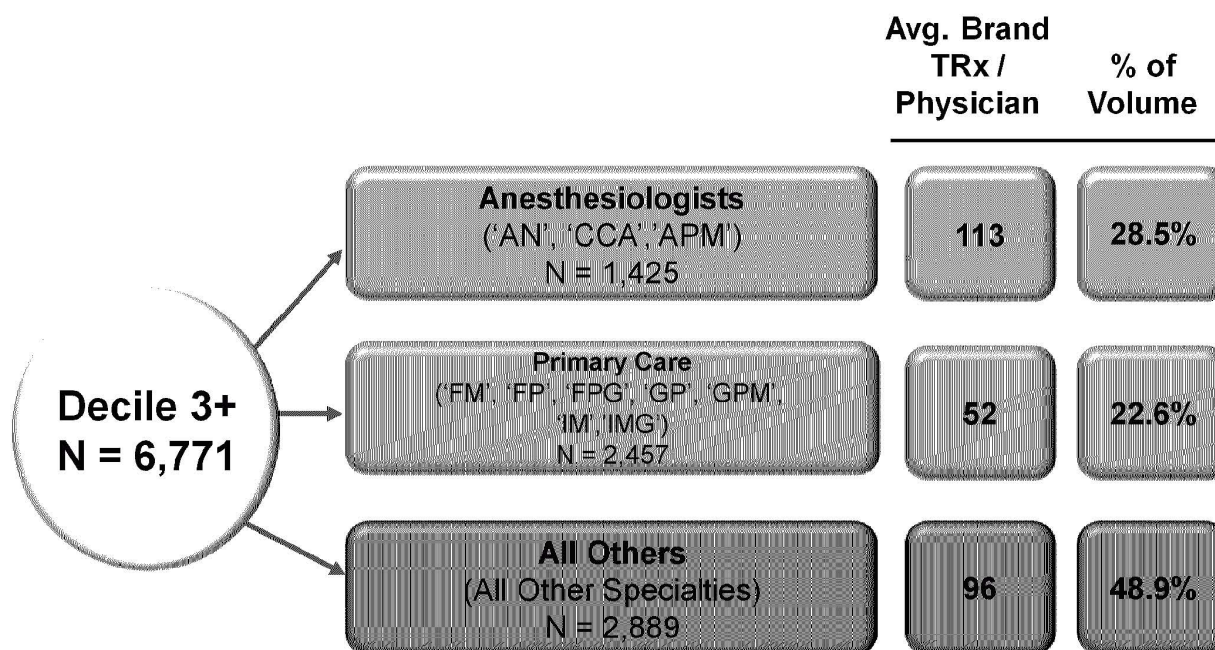


28

Kadian Specialty Aggregation (Dec '07-Nov '08)

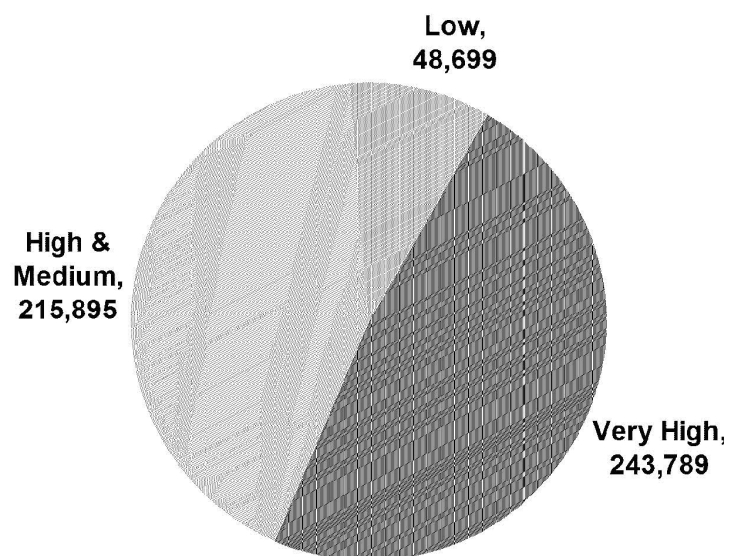
Deciles 3+ Physicians

- The average TRx volume per physician is the highest at 113 for anesthesiologists and only 53 for PCPs.
- Anesthesiologists account for nearly 28.5% of the Kadian TRx volume with 21% of the physicians.

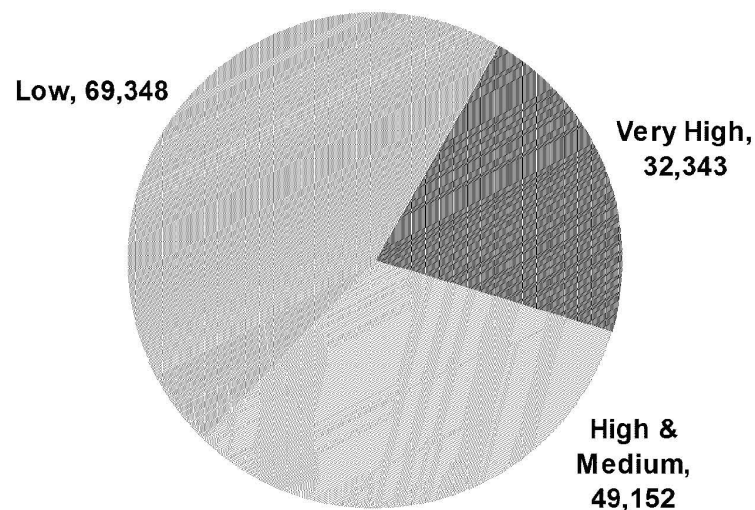


Kadian TRxs For Kadian Volume Segments Detailed and Non-Detailed Physicians in 2007

Detailed Physicians



Non-Detailed Physicians



Detailing By Physician Segment in 2007*

- Data in the chart below are for physicians who were detailed in 2007 and wrote Kadian. There was an additional 2,107 mostly low volume physicians who were also detailed that year, but did not prescribe Kadian at all.
- The total number of calls made by Alphasigma reps in 2007 were 164K and this increased to 229K in 2008.

Specialty	Kadian Volume	Number of Physicians	Kadian TRx Volume	Historical PDEs (2007)	PDEs: 25% Reduction	PDEs: 50% Reduction	PDEs: 75% Reduction
Anesthesiologists	VH	287	88,259	25.6	19.2	12.8	9.6
Anesthesiologists	H&M	865	56,559	18.6	14.0	9.3	7.0
Anesthesiologists	L	620	5,565	11.3	8.5	5.6	4.2
Primary Care	VH	73	21,664	21.7	16.3	10.8	8.1
Primary Care	H&M	1,468	67,332	13.3	10.0	6.7	5.0
Primary Care	L	4,520	32,939	8.6	6.5	4.3	3.2
Others	VH	422	123,221	25.6	19.2	12.8	9.6
Others	H&M	1,580	96,612	16.7	12.5	8.3	6.3
Others	L	2,258	1,723	9.6	7.2	4.8	3.6
Total	All	12,093	493,874	149,491	112,118	74,746	56,059



* Actual data period is from Dec '06 through Nov '07. A total number of 14,200 physicians received 164K calls during 2007.



31