



Sanofi et al. v. Merck
1:16-cv-812-RGA

PTX-0739

**Lantus COMPASS: Wave 2 (Sep-Oct 2007)
Final Report**

Presented: November 29, 2007

COMPASS

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SANOFI3_90330807

**PTX-0739.0001
Sanofi Exhibit 2146.001
Mylan v. Sanofi
IPR2018-01675**



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The COMPASS study uses a consistent and flexible framework for monitoring product performance drivers across sales and marketing

COMPASS Study Objectives

- Provide more comprehensive, in-depth analysis of key issues
- Provide continuous marketing insights with the ability to drill down as needed
- Provide insights across brands to enhance organizational learning, while maintaining the customization required for each unique brand

Physician ATU Tracking Study

This survey focuses on the product perceptions of the target audience

- Sampling: specialty
- Method: Internet
- Timing: cumulative knowledge buildup
- Goal: identify opportunities
- Modules include:
 - Awareness, Trial, and Usage
 - ADA Insulinization Guidelines ***New***
 - TZD Safety Issues ***New***
 - Pen Devices ***New***
 - Treatment Protocol
 - Product Perceptions, Positioning
 - Sampling

Sales Force Tracking Study

This survey focuses on specific sales force interactions

- Sampling: company and specialty
- Method: Internet
- Timing: most respondents were detailed within 24 hours of a sales call, and the rest were detailed between 2 to 7 days of a sales call
- Goal: monitor implementation
- Modules include:
 - Sales Force Activity Tracking
 - Message Delivered / Effectiveness
 - Sales Call Quality
 - Patient Flow ¹
 - Sales Rep Quality / Value Proposition
 - Overall Company Reputation



Note: ¹Patient Flow section moved from ATU to SF survey in Sep-Oct '07 to utilize larger sample size.



For the Sep-Oct '07 wave, we recruited physicians from quintiles 3 – 5 in the Select Insulin Market

Physician ATU Tracking Study

This study focuses on the product perceptions of the target audience

8/29/07 – 9/4/07: Sample n = 201

Specialty	Count
PCP	125
Endo	76
Total	201

Sales Force Tracking Study

This study focuses on specific sales force interactions

***8/29/07 – 10/19/07: Sample n = 682**

Product	PCP	Endo	Total
Lantus	76	50	126
Byetta	75	43	118
Humalog 75/25 or 50/50	75	28	103
Levemir	76	50	126
Novolog 70/30	76	29	105
Januvia	75	29	104
Total	453	229	682

In the Sales Force Tracking Study, the goal is to interview physicians as close to the product detail as possible → 70% of respondents were surveyed within 24 hours of their last detail, while the remaining 30% were surveyed within 2-7 days



Note: Recruiting database sourced from POA2 2007, quintiles 3-5 targets in the Select Insulin Market. *69 PCPs and 73 Endos took the survey for multiple companies. Responses for non-quota group questions are taken from their first survey.



Weighting was applied to both studies in order to adjust the data to better reflect the target population

Physician ATU Tracking Study

Data collected in the ATU Tracking Study is either weighted by *population weight* or by *population and patient weight*:

- The population weight ensures that the results reflect the specialty mix in the medium and high quintile prescriber universe
- The patient weight ensures that the results represent the patient universe (population weight factored by the number of Type 2 diabetes patients treated)

Sales Force Tracking Study

The Sales Force Tracking Study uses the *population and reach weight*:

- The reach weight ensures that the results reflect the reach with which physicians are called upon by sanofi-aventis and competitors





Statistical testing at the 95% confidence level is represented consistently throughout the report

◆ Current wave to previous wave

- Represented by an asterisk (*) OR by an up / down arrow and the value from the previous wave (if data from previous wave is not shown in chart)
- *Example:* Levemir detailing is significantly higher in Mar-Apr '07 than in Sep-Oct '06

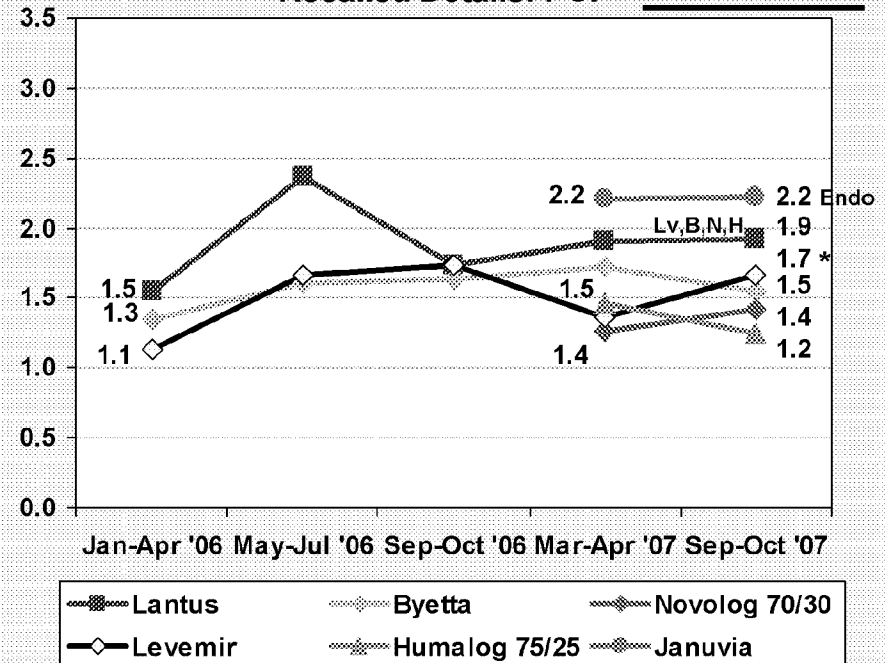
◆ Between Segments

- Abbreviations are placed next to the segment which is significantly greater:
 - PCP = PCP, Endo = Endo
 - User = U, Non-User = NU
 - High Share = H, Low Share = L
- *Example:* PCPs recall significantly more Januvia details than Endos
- Segmentations other than Specialty are also defined in the slide footnote

◆ Between Products

- Abbreviations are placed next to the product which is significantly greater:
 - Lantus = L, Levemir = Lv, Lantus Intensive = Li, Byetta = B, Premix = P, Januvia = J, Exubera = E, Novolog = N, Humalog = H, Apidra = A, NPH = NPH
- *Example:* Januvia detailing is significantly higher than all other products
- If chart becomes crowded, stat testing may be shown in table form ("X" indicates significance between products)

Recalled Details: PCP *Illustration*



PCP	L	B	N	Lv	H	J
L		X	X	X	X	X
B			-	-	X	X
N				X	X	X
Lv					X	X
H						X
J						



All other stat testing symbols are defined on the relevant slides



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Key Findings: Sept-Oct 2007 COMPASS

◆ Past vs. Intended Prescribing

- Physicians intend to decrease prescribing of TZDs and SUs and increase prescribing of DPPIVs and Byetta
- Physicians do not intend to increase prescribing of Levemir; they expect to write somewhat less Premix and a little more Byetta

◆ TZDs - Impact of Avandia News

Direct Switching of TZD Patients to Insulin as a Result of Avandia Safety Concerns Was Perceived to Be Rare One-Fifth of Physicians Expect One of the Ultimate Effects, However, to Be a 7-8 Month Decrease In Avg Time-To-Insulin

- Physicians are evenly split on whether Avandia CV safety news is a class effect - many don't know (even split among Y/N/DK)
- PCPs say about half of their Avandia patients have asked about the news, while Endos say 70% have asked
- Despite uncertainty as to whether CV risks are a class effect, 45% of PCPs and 40% of Endos report the Avandia news is extremely influential (6-7) on their prescribing of Actos
- Two-thirds of physicians have reduced the number of new Avandia prescriptions, by an average reduction of 70%
- Very few Avandia patients were switched to insulin - less than 5%
 - Approximately 70% of Avandia patients either *continued treatment with Avandia* or *switched to another oral drug class*;
 - Of those switching to another oral, the most common choice was Actos followed by DPPIVs;
- One-fifth of physicians report that it is *extremely likely* (6-7), however, they will initiate insulin sooner as a result of the Avandia safety concerns - 7 months sooner for PCPs and 8 months sooner for Endos.

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Key Findings: Sept-Oct 2007 COMPASS

◆ High Awareness & Perceived Impact of ADA Guidelines On Time To Insulin

- Nearly half of PCPs and one-third of Endos say they are extremely likely (6-7) to initiate insulin sooner as a result of the 2006 ADA guidelines - an average of 7 months sooner
- For patients uncontrolled on 2 orals, physicians report a significant increase in *adding other insulin options* - driven by Premix among PCPs; likelihood of adding other oral agents decreased, likely due to the emergence of TZD safety risks

◆ SoloSTAR Is Doing Well

- **High Awareness:** 90% of physicians have heard of SoloSTAR, up from only 51% in the March-April '07 fielding of COMPASS.
- **Relatively High Usage:** Nearly 60% of physicians currently use SoloSTAR with their patients.
- **1/2 New Lantus Users, 1/2 Cannibalization :** Physicians perceive that 8% of their Lantus patients use SoloSTAR. Among them,
 - 47% are new to Lantus (of those, 65% are new to insulin)
 - 33% switched from the vial/syringe, and
 - 20% switched from OptiClik.
- **Well-Rated:** Physicians rate SoloSTAR as the best-performing pen device in a statistical tie with FlexPen. And, 46% of physicians consider SoloSTAR to be either much better or slightly better than Novo's FlexPen in overall performance. Among those physicians, 65% cite 'ease of use' as the primary reason why SoloSTAR is better than FlexPen.

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Key Findings: Sept-Oct 2007 COMPASS

◆ Little Change In Attribute Importance for a Diabetes Product, But Ratings AND Rankings Need to Be Considered To See Full Picture

- **A1C Less Important, But Still Top of List:** 75% of physicians rated importance of "Glucose control (HbA1c levels <7)" as a 6 or a 7, vs. 84% in prior wave, a significant decrease
- **Once Daily Dosing:** 30% of physicians choose *Once daily dosing* among their top 5 most important attributes, which places it sixth in importance rankings, despite being rated as 14th most important
- **Weight attributes continue to be among least important** and importance ratings have for the most part returned to 2005 levels.
- **Promotes weight loss**, however, is ranked among the top 5 most important attributes by 26% of physicians despite being rated 18th most important
- **Beta-Cell Preservation Less Important:** 51% of physicians rated importance of "Preserves beta-cells/slow disease progression" as a 6 or a 7, vs. 68% in prior wave, a significant decrease

◆ Continued Convergence of Satisfaction Ratings for Levemir/Lantus Premix At Peak Performance Rating for Efficacy Attributes

- Sep-Oct '07 showed a continued convergence of physicians' overall satisfaction with Lantus and Levemir therapies (ie less differentiation)
- Physicians perceive consistent performance on efficacy attributes over the past 12 months for most therapies; however, Premix is at the peak of its performance range.

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Key Findings: Sept-Oct 2007 COMPASS

- ◆ **Lantus Has Lost Significant Ground To Levemir With PCPs In Differentiation On Key Efficacy & Safety Attributes, But Lantus Differentiation Among Endos Appears To Have Stabilized**
 - 86% of PCPs now say they currently use Levemir, up significantly from 62%
 - Lantus lost significant ground in its lead over Levemir among PCPs on 8 of 11 efficacy & safety attributes but gained ground directionally with Endos on 9 of them
 - Lantus lost ground directionally to Levemir on weight attributes – and is now disadvantaged, but continues to hold an advantage on all dosing related attributes
 - The majority of physicians believe Lantus and Levemir perform similarly on the top 10 attributes; the percentage of PCPs rating Lantus superior to Levemir decreased on several of these attributes since the prior wave
 - Unaided, 30% of physicians believe there is little or no difference between Lantus and Levemir
 - Unaided, 21% of Endos report QD vs. BID dosing as a major difference between Lantus and Levemir; 38% of physicians mention QD dosing when asked about Lantus' single greatest advantage over Levemir
 - While PCPs report that a similar number of their patients take Lantus once per day in Mar–Apr '07 and Sep–Oct '07, Endos reported a significant decrease in the number of QD Lantus patients
 - Perceptions of Levemir dosing have remained stable over the past year: PCPs dose Levemir b.i.d. for 18% of patients, while Endos report 40% of Levemir use is b.i.d.
 - Perceptions of Lantus dosing have increased significantly towards b.i.d.: among Endos dose Lantus b.i.d. for 16% of patients vs. 11% in prior wave

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Key Findings: Sept-Oct 2007 COMPASS

◆ **Pre-Mix**

- Pre-mix BID continues to erode Lantus' advantage on several of the top 10 attributes, especially on *24 hour glucose control* and *low incidence of symptomatic hypoglycemia*
- Physicians perceive Lantus with Orals overall to still be equivalent or superior to Premix BID across the top 10 attributes with the exception of, not surprisingly, *effective in lowering PPG*

◆ **Physician Interest In Byetta Appears To Be Waning**

There Has Been Little Change In Lantus Differentiation vs. Byetta On Key Attributes

- Significantly more PCPs say they tried but discontinued using Byetta: 9% up from 1%
- Lantus' performance advantage over Byetta on *glucose control* attributes remains strong in Sep-Oct
- Roughly 50% of physicians perceive Lantus with Orals as superior to Byetta with Orals on efficacy attributes

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Key Findings: Sept-Oct 2007 COMPASS

◆ **Message Association**

- *In Sep-Oct '07, Lantus maintained its ownership of Provides once-daily dosing while Levemir captured increasing share of other important attributes including Provides 24 hour control with one daily injection*
- *This is important because NRx share analysis shows that once daily dosing and 24-hour control with one injection are the most important attributes (derived) when choosing between Lantus and Levemir*
- *Lantus significantly increased ownership of Glucose control, as defined by HbA1c<7, up to 38% from 32%. This came at the direct expense of Premix*
- *Physicians associate Lantus with the message Has the best pen device more than any other product, likely due to the SoloSTAR launch*

◆ **Sales Force Messaging**

- ***SoloSTAR Pen Is #1 Recalled Main Message for Lantus Details, cited by 28% of physicians, followed by efficacy (23%), duration of action/24-hr (22% and down from 48% in May-July 2006)***
- ***Recall of Specific SoloSTAR Messages Is High: >50% of physicians detailed on SoloSTAR recalled hearing 6 out of 8 discussion topics related to SoloSTAR***
- ***Less Weight Gain is #1 Recalled Main Message for Levemir Details, cited by 33% of physicians, followed by duration of action/24-hr (27%)***
- ***Byetta Details Continue to Focus on Weight Loss (stable at 48%) and A1c Control (27%).***

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Key Findings: Sept-Oct 2007 COMPASS

◆ Sales Force Resources & Activities

- Physician recall of the frequency of Novo sales calls indicates a significant increase in Novo monthly call activity among PCPs, from 1.5 to 1.7.
- Lantus maintains a competitive share of voice, with a 25% share of recalled details vs. 21% for Levemir among select insulins & Byetta.
- PCPs are giving more time to Levemir reps and report the highest percentage of new learnings.
 - PCPs gave Novo reps 10.2 minutes for Levemir calls, while they only gave on average 6.2 minutes for Lantus - Novo is doing more lunch/break room details while Lantus more hallway calls.
 - Duration of the physician's relationship with the representative does not vary significantly for among diabetes sales forces for key products in this market.
- Use of the various sales rep resources differs marginally by company; one-quarter of physicians were not shown any materials in their last Lantus detail
- Directionally, Lantus reps leave samples and identify patients appropriate for therapy less often than do competitor reps

◆ Sales Rep Ratings

- Directionally, Novo Nordisk's diabetes sales force is considered "best in class" by the highest percentage of physicians: 25%-30% of physicians choose Novo while 23%-25% choose sanofi-aventis, but each company's individual ratings in this category differ by one only percentage point.

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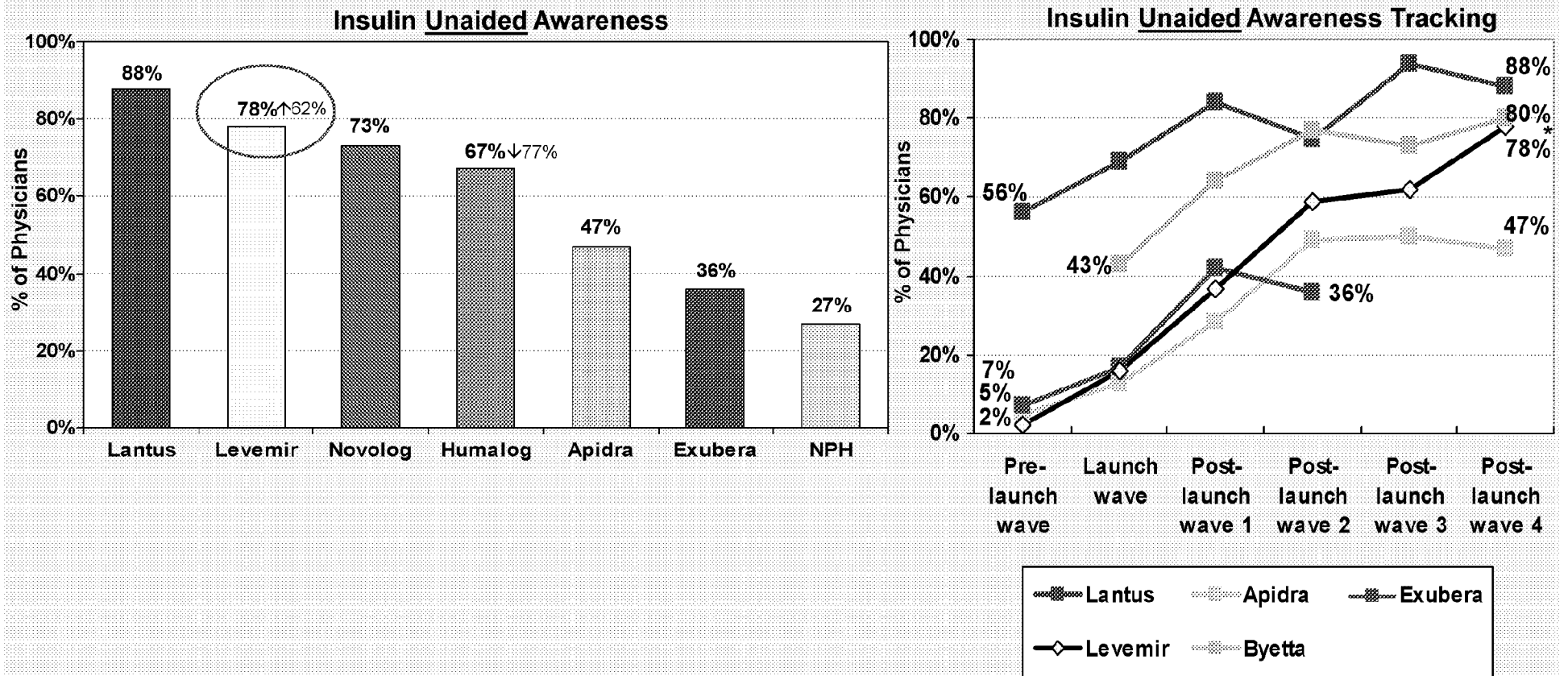
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Unaided awareness of Levemir increased significantly, but is below Lantus awareness levels in the fourth wave post-launch

Unaided Product Awareness: Total



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population. AWR0: What insulin agents are you aware of for the treatment of diabetes? For Lantus, Pre-launch wave =Baseline (April '01 fielding), Launch wave=Month 1 (Jun - Jul '01 fielding), Post-launch wave 1=Month 2 (Aug '01 fielding), Post-launch wave 2=Month 5 (Nov '01 fielding), Post-launch wave 3=Month 9 (Mar '02 fielding), Post-launch wave 4=POA302 (Jul - Oct '02 fielding). No pre-launch data available for Byetta



Total 201 16

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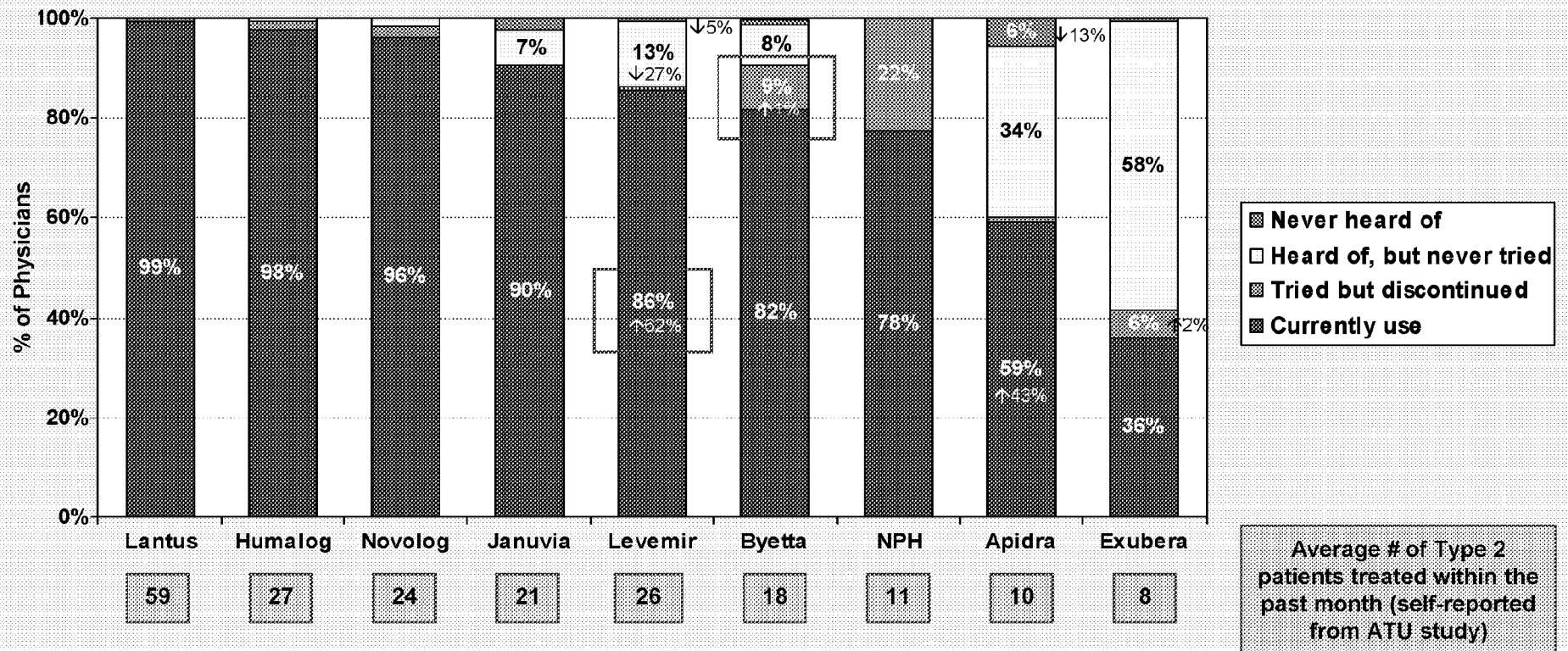
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The percentage of PCPs currently using Levemir (self-reported) increased in Sep-Oct '07 to 86%; discontinuation of Byetta increased from 1% to 9%

Aided Product Awareness: PCPs



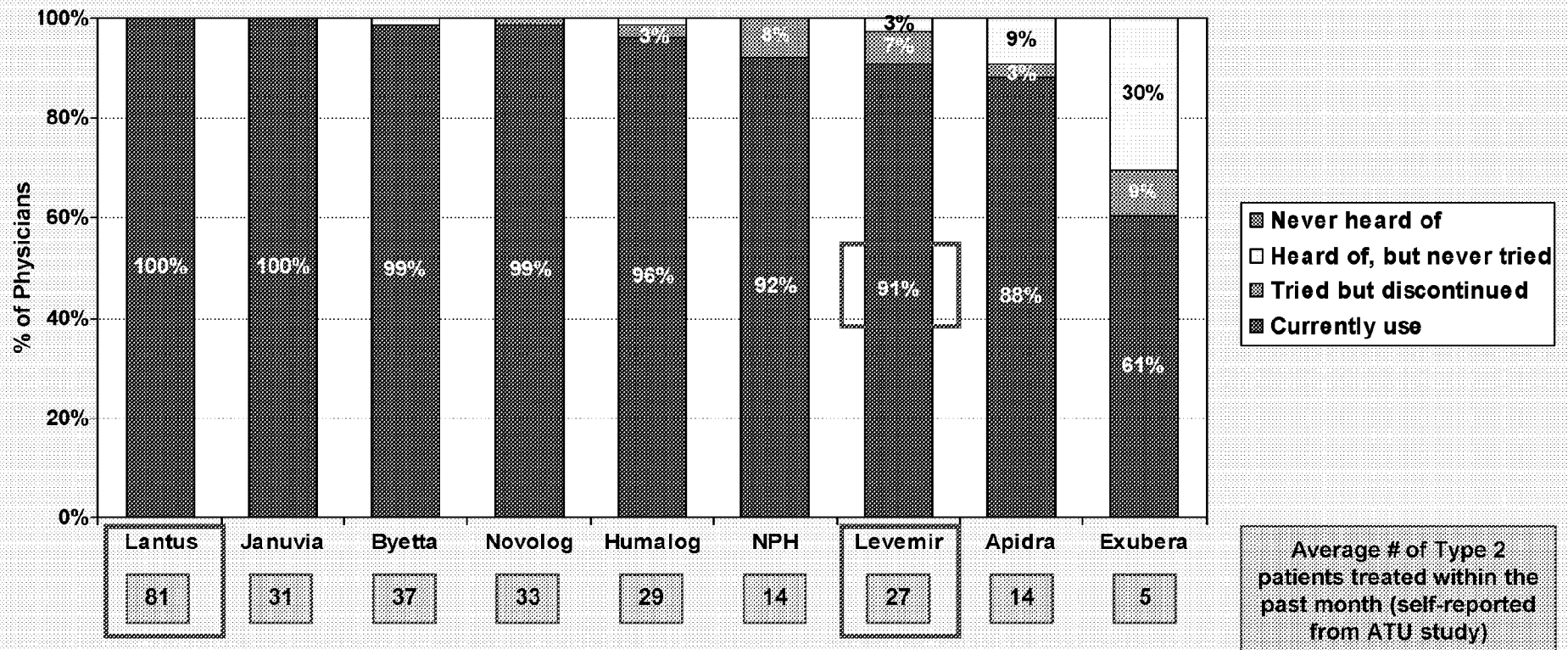
Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. Statistical testing by response across products shown in appendix. AWR1: Please indicate your experience with each of the following diabetes products. Average number of patients treated in past month based on Type 2 patient base (BS2A) and self-reported prescribing (BS9).

PCP	125
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91% of Endos report currently using Levemir; however, physicians believe they prescribe Levemir for 1/3 as many patients as Lantus

Aided Product Awareness: Endos



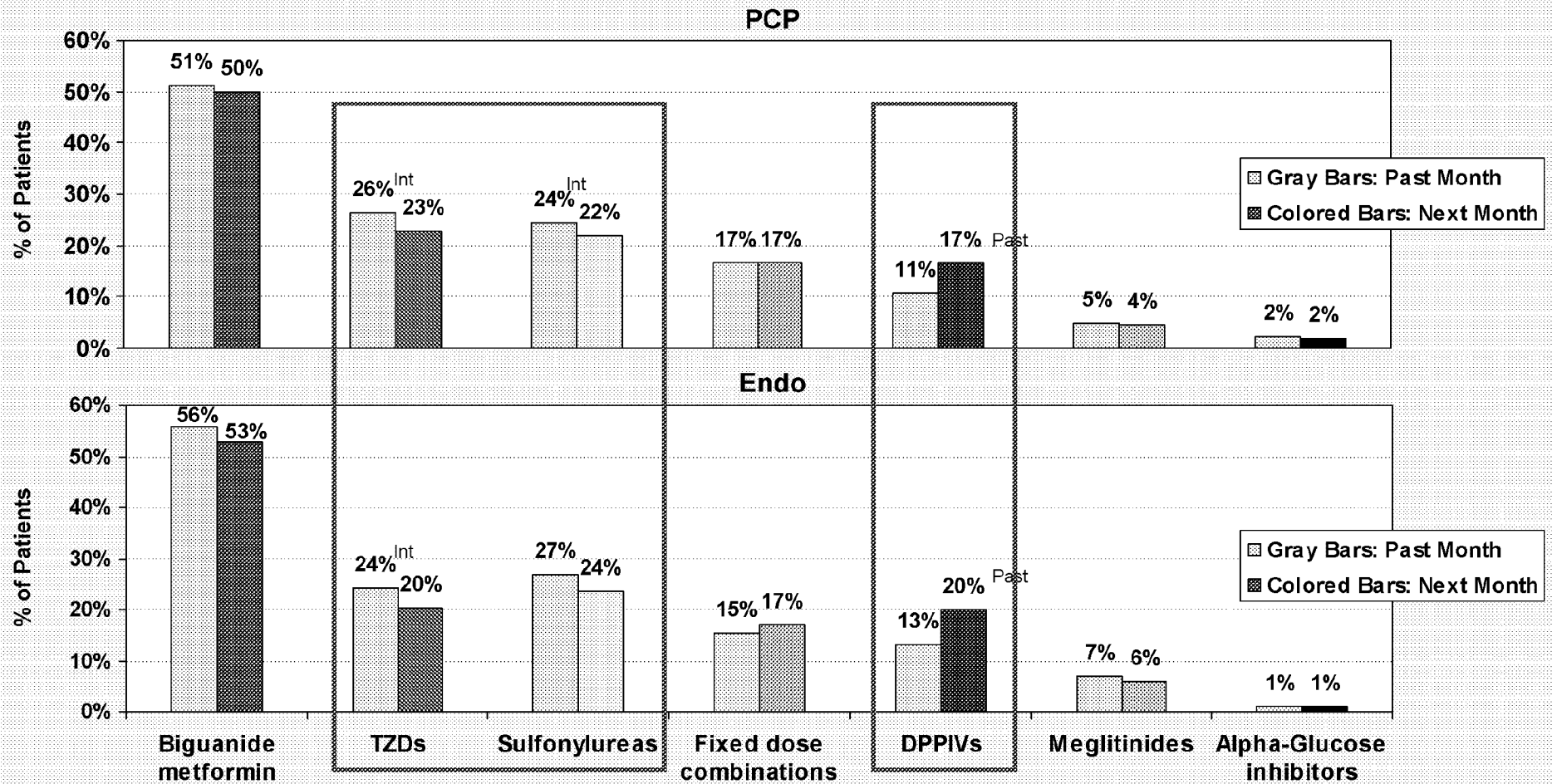
Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. Statistical testing by response across products shown in appendix. AWR1: Please indicate your experience with each of the following diabetes products. Average number of patients treated in past month based on Type 2 patient base (BS2A) and self-reported prescribing (BS9)

Endo	76
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Physicians intend to decrease prescribing of TZDs and SUs and increase prescribing of DPPIVs

Past and Intended Prescribing of Oral Therapies for Type 2 Patients: by Specialty



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population and patient base. BS7: Thinking of your LAST 100 Type 2 diabetes patients taking ORAL diabetes medications (regardless of concomitant use of insulin or Byetta), what percentage received the following treatments?

BS8: Thinking of your NEXT 100 Type 2 diabetes patients taking ORAL diabetes medications (regardless of concomitant use of insulin or Byetta), what percentage will receive the following treatments?

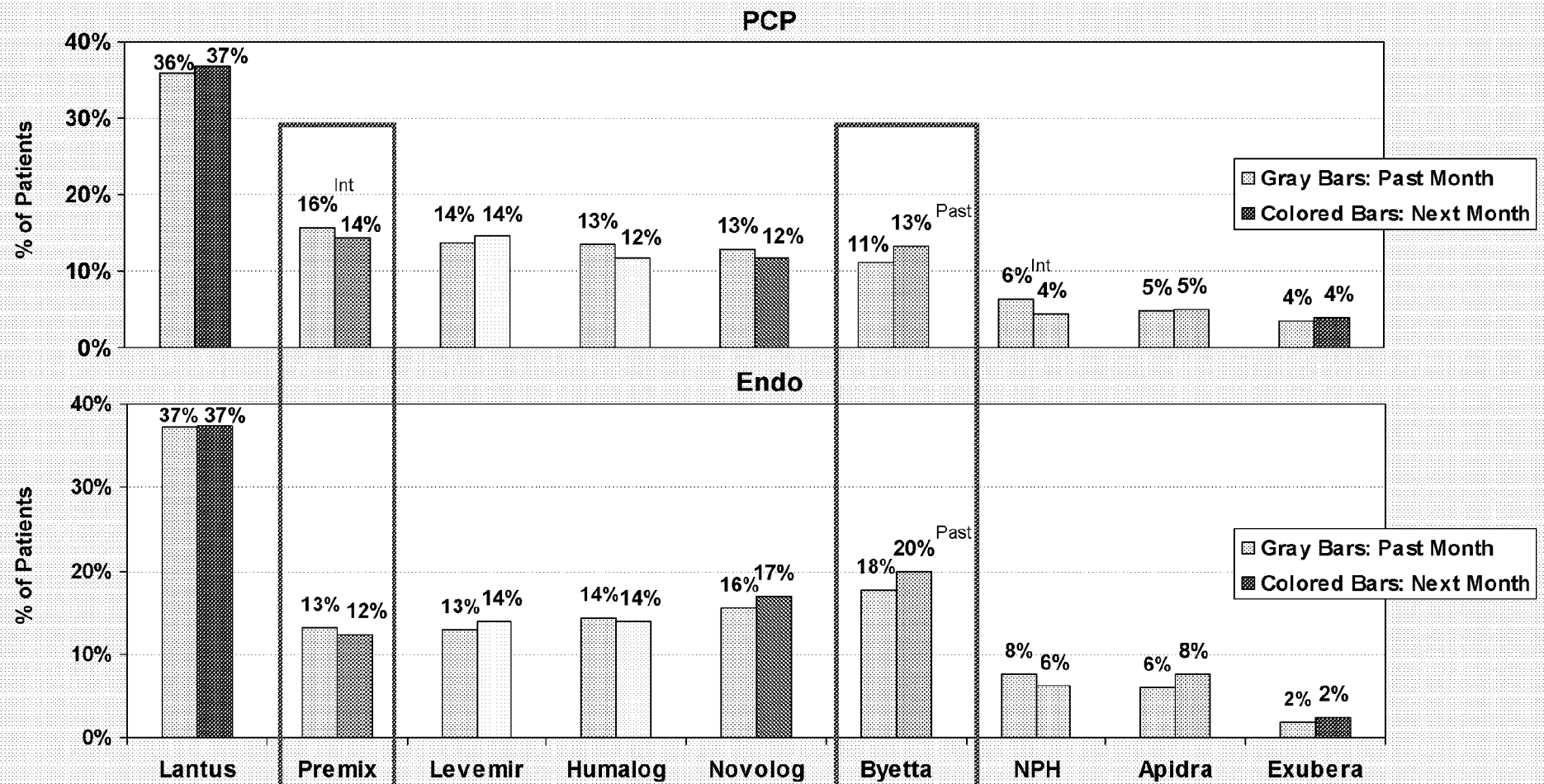


PCP	125
Endo	76



Physicians do not intend to increase prescribing of Levemir; they expect to write somewhat less Premix and a little more Byetta

Past and Intended Prescribing of Insulin or Byetta for Type 2 Patients: by Specialty



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population and patient base. BS9: Thinking of your LAST 100 Type 2 diabetes patients taking BYETTA OR INSULIN (regardless of concomitant use of oral diabetes medications) what percentage received the following treatments: BS10: Thinking of your NEXT 100 Type 2 diabetes patients taking BYETTA OR INSULIN (regardless of concomitant use of oral diabetes medications) what percentage will receive the following treatments

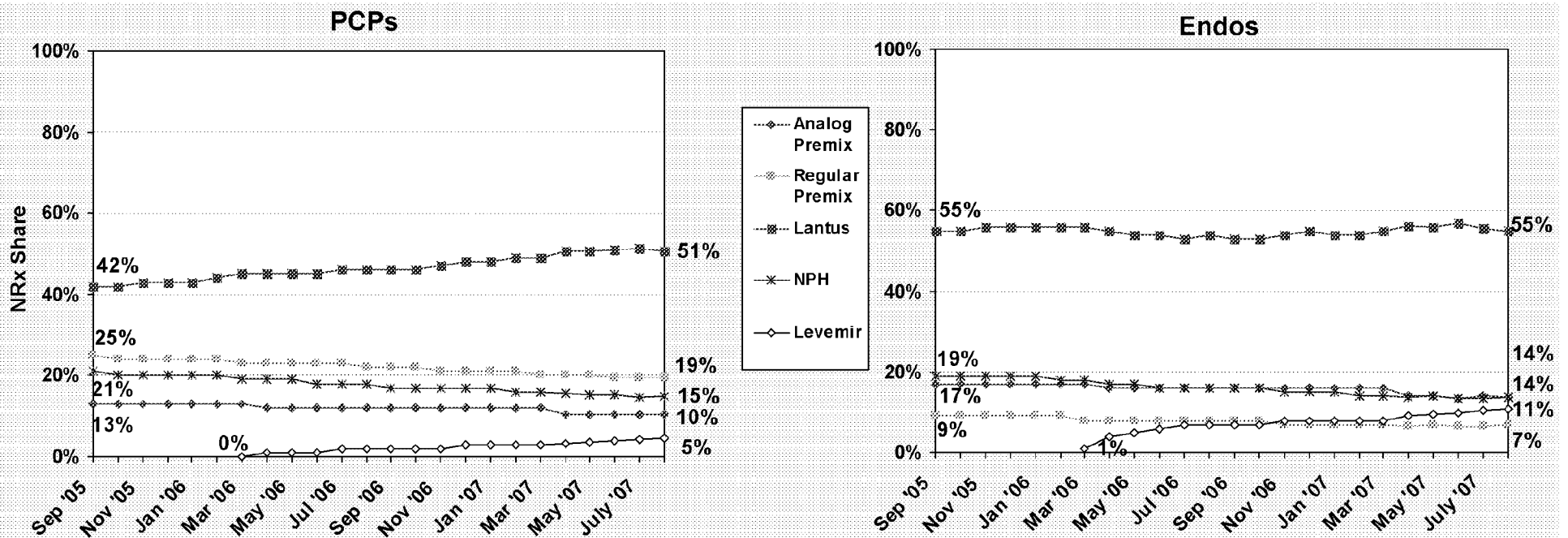


PCP	125
Endo	76



Lantus NRx continue to increase among PCPs, now capturing over 51% of new prescriptions written; Levemir accounts for only 5% of new PCP prescriptions

Universe NRx Market Share: by Specialty



Source: IMS Health Confidential Proprietary
 Note: IMS Health Incorporated, Xponent NRx share of select insulin market from Sep '05 to Aug '07. PCPs include GPs, FGPs, FPs, IMs, IFPs. Endos include DIAs, ENDS, ENRs.



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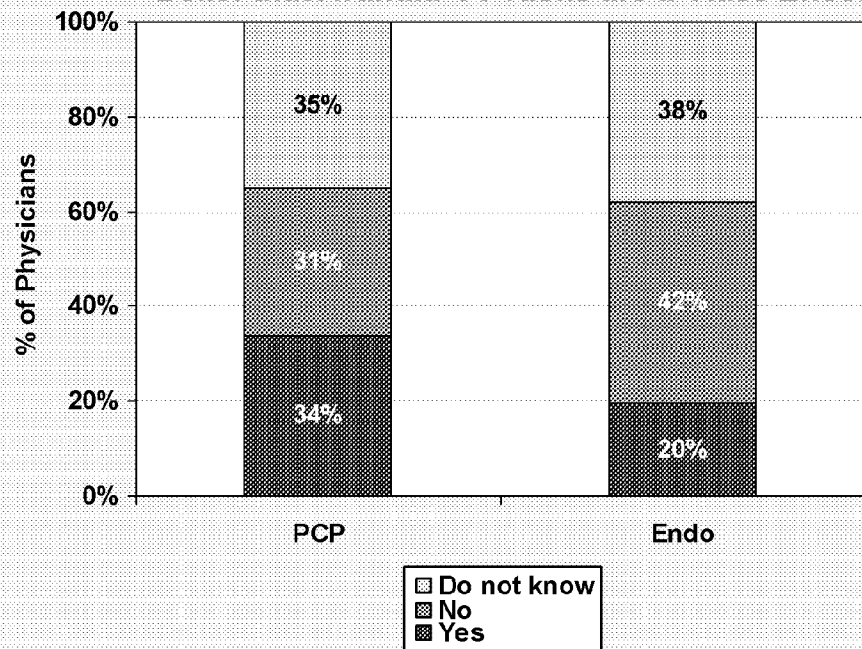


Only one-third of PCPs and 20% of Endos believe the link between Avandia and increased cardiovascular side effects is a class effect and the majority of Avandia patients have asked them about the news

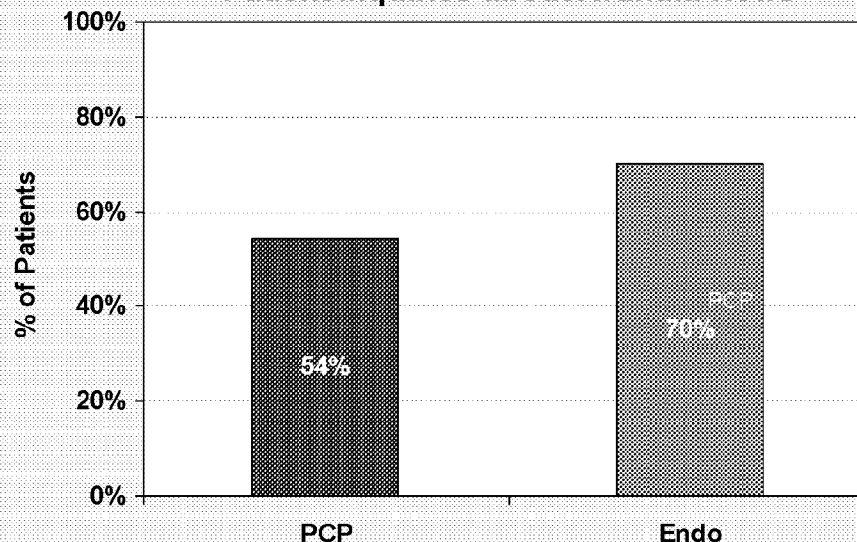


Awareness of Avandia Cardiovascular Risks: by Specialty

Belief that Avandia CV Risks are a Class Effect



Patient Inquiries about Avandia News

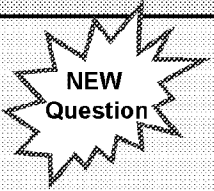


Source: COMPASS Physician ATU Tracking Study

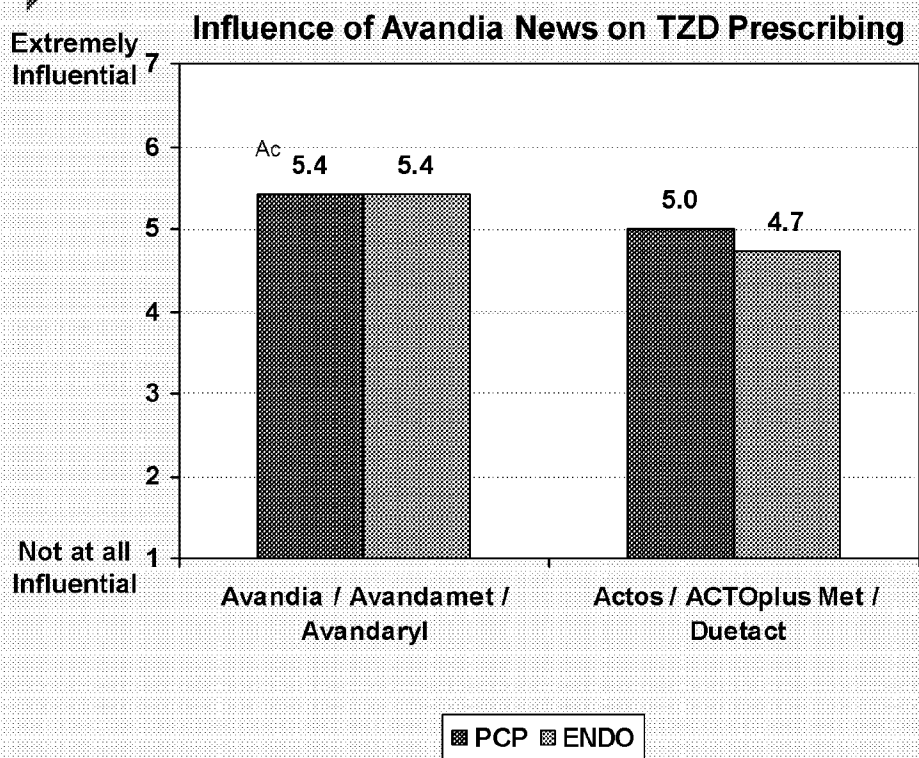
Note: Data are weighted by physician population and patient base. TZD1: Considering the recent news linking Avandia to a possible increased risk of cardiovascular side effects, do you believe this to be a class effect? TZD2: What percentage of your patients using Avandia / Avandamet / Avandaryl in the past six months have inquired about the news events?

Sep-Oct 0	
TZD1 - PCP	44
TZD1 - Endo	32
TZD2 - PCP	125
TZD2 - Endo	76

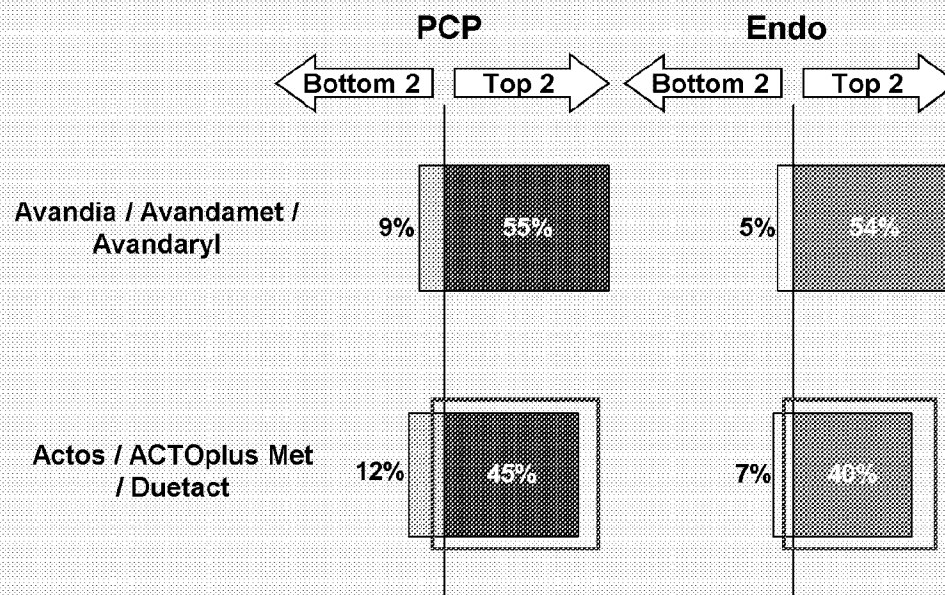
Despite uncertainty as to whether CV risks are a class effect, 45% of PCPs and 40% of Endos report the Avandia news is extremely influential (6-7) on their prescribing of Actos / ACTOplus Met / Duetact



Influence of Avandia News on TZD Prescribing: by Specialty



Top / Bottom Box Ratings



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population. Significantly different at 95% between products within a specialty as noted: Ac = Actos / ACTOplus Met / Duetact. TZD3: On a scale of 1-7, how influential have these issues been on your decision to prescribe Avandia / Avandamet / Avandaryl? TZD4: On a scale of 1-7, how influential have these issues been on your decision to prescribe Actos / ACTOplus Met? / Duetact?

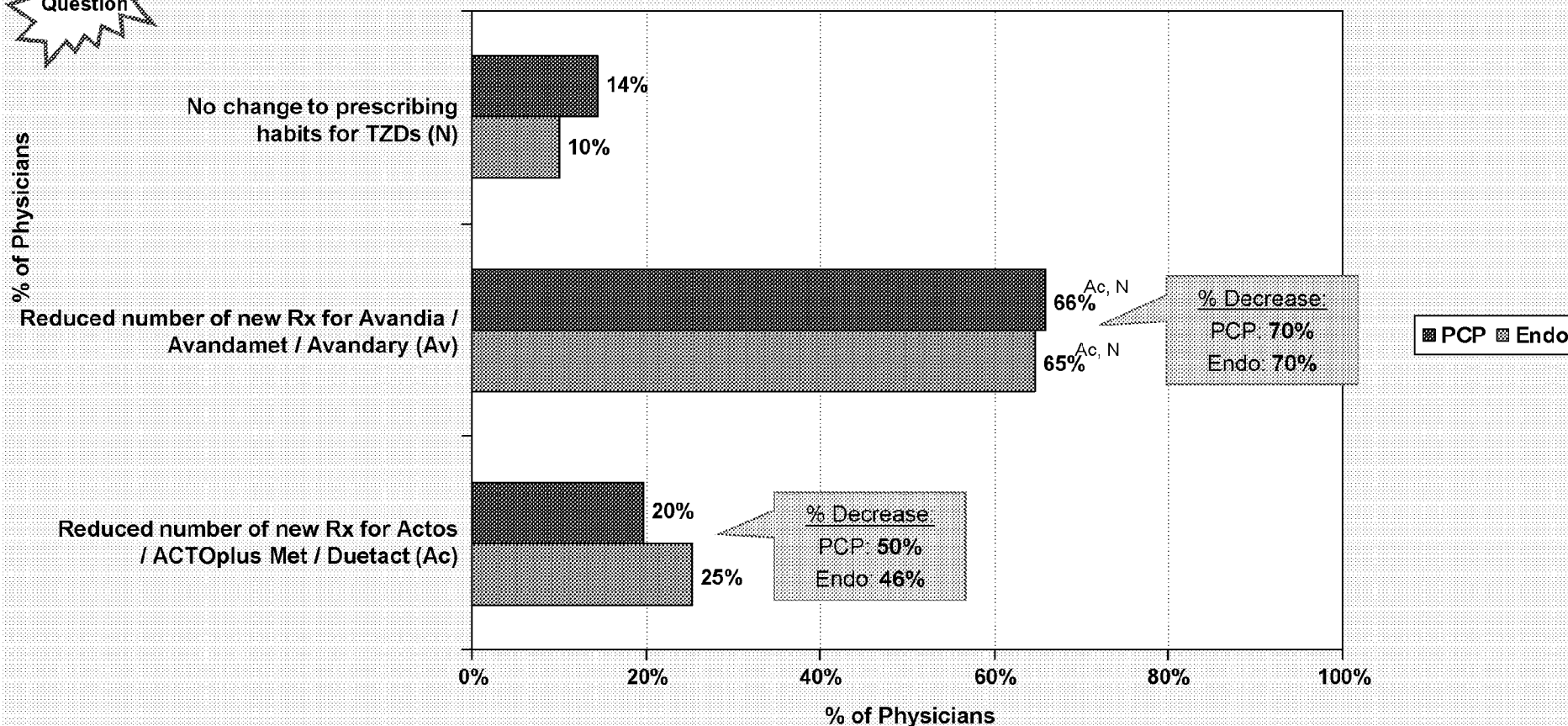
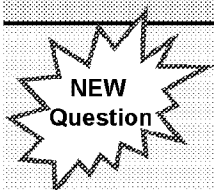


PCP	125
Endo	76

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Two-thirds of physicians have reduced the number of new Avandia prescriptions, by an average reduction of 70%

Impact of Avandia CV Risk on New Patients: by Specialty



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. Statistically different at 95% between prescribing change as noted in data labels.
 Not statistically different at 95% between specialties. TZD6: How has the Avandia news affected your prescribing habits for new patients? TZD6B.C. By what percent have you reduced your new prescriptions written for [Avandia / Avandamet / Avandary] / [Actos / ACTOplus Met / Duetact]?

Specialty	N
PCP	125
Endo	76

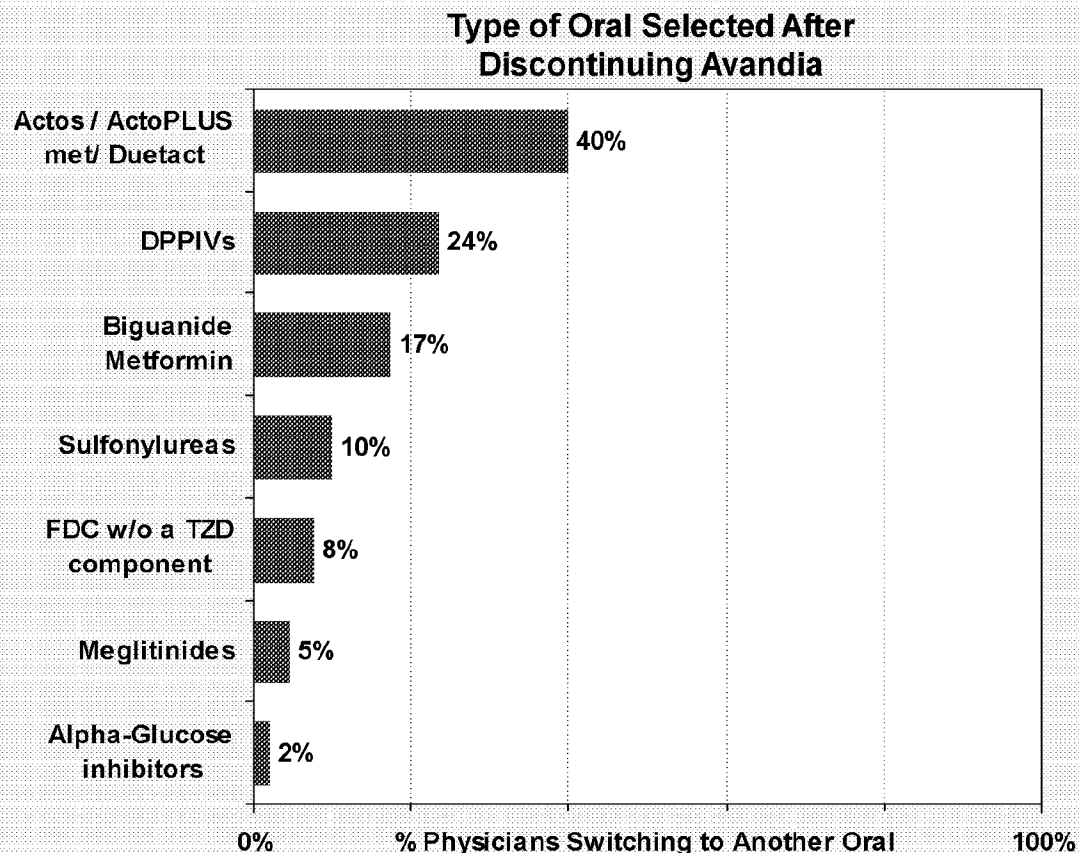
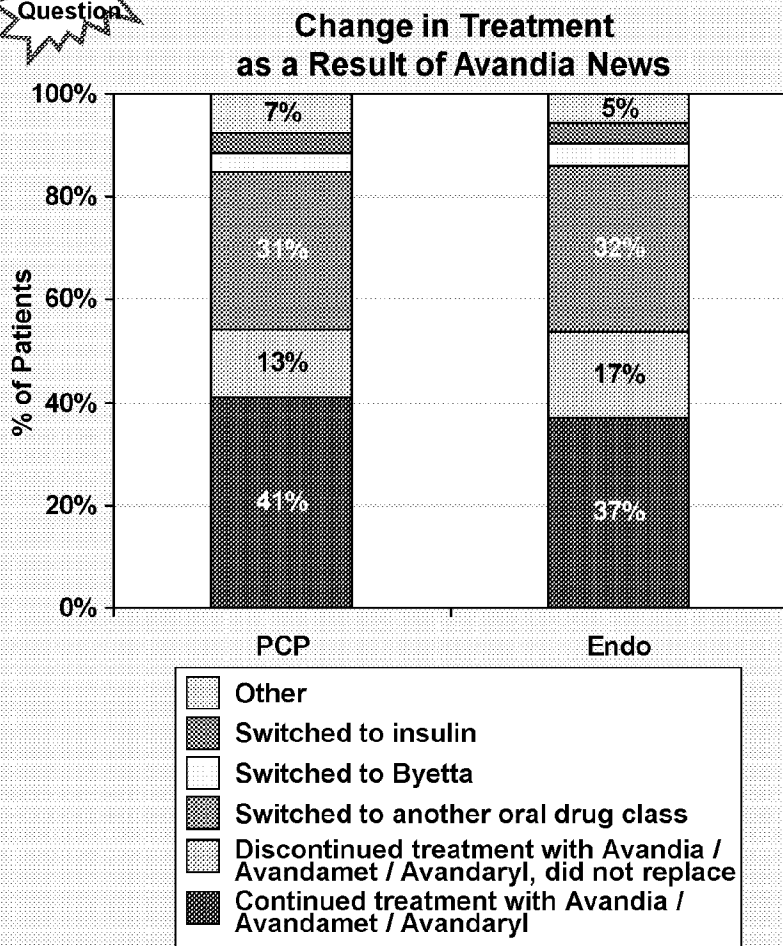
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Approximately 70% of patients on Avandia either *continued treatment with Avandia* or *switched to another oral drug class*; of those switching to another oral, the most common choice was Actos followed by DPPIVs



Impact of Avandia CV Risk on Current Patients: by Specialty



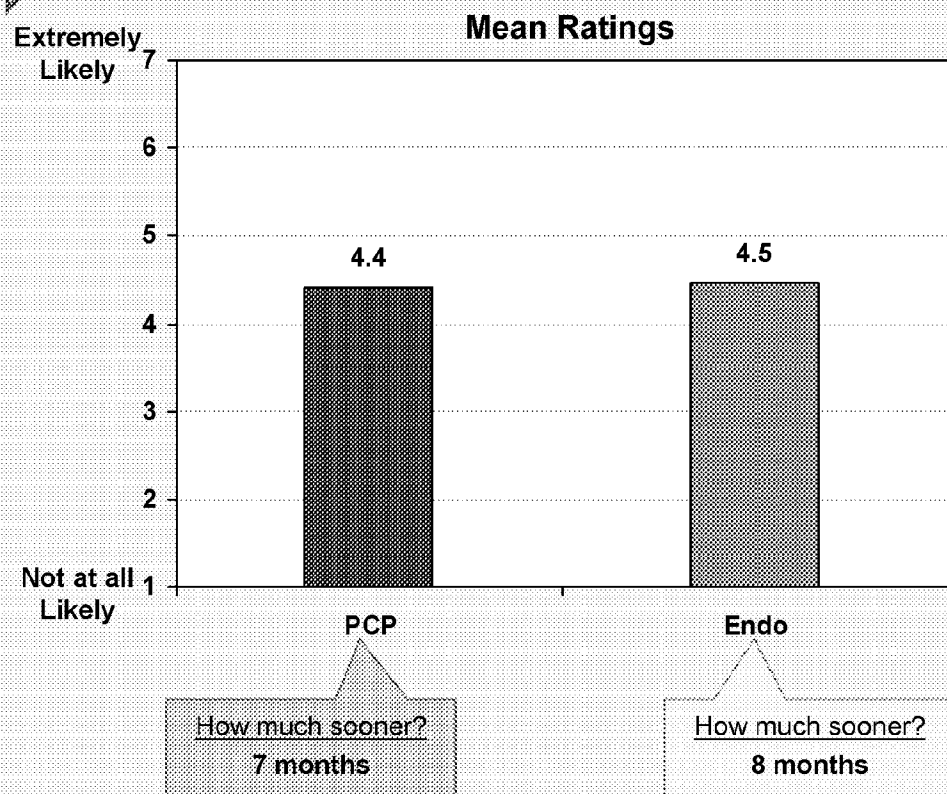
Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by patient base. Statistical testing across therapies shown in appendix. TZD5: Considering your patients who were taking Avandia / Avandamet / Avandaryl at the time when the information about the potential link to cardiovascular side effects was released (May- June 2007), what percentage... TZD7: Of the Avandia / Avandaryl / Avandamet patients you have switched to another oral diabetes medication, to what percent have you prescribed each of the following?

Sep 06-07	
TZD5 - PCP	125
TZD5 - Endo	76
TZD7	166

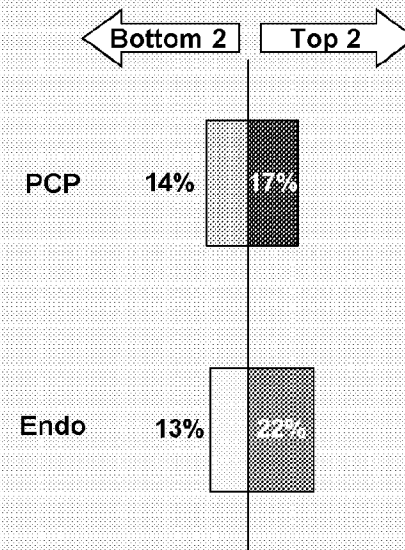
One-fifth of physicians report that it is *extremely likely* (6-7) they will initiate insulin sooner as a result of the Avandia safety concerns



Likelihood of Earlier Insulinization Due to TZD Safety Risks: by Specialty



Top / Bottom Box Ratings



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. TZD8: As a result of the Avandia safety concerns, how likely are you to initiate your patients on insulin sooner? If TZD8 >=4, then TZD9: How much sooner are you likely to initiate your patients on insulin as a result of the Avandia safety concerns?

Specialty	
TZD8 - PCP	126
TZD8 - Endo	76
TZD9 - PCP	101
TZD9 - Endo	59



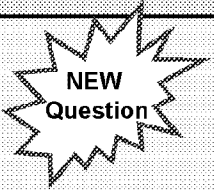
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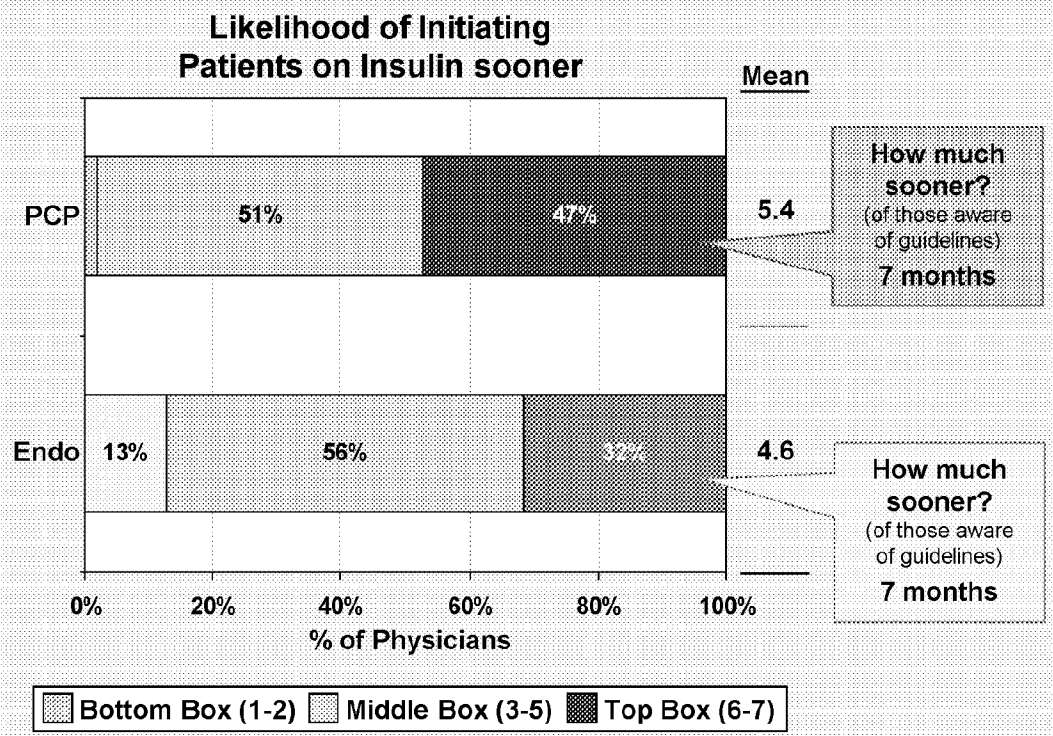
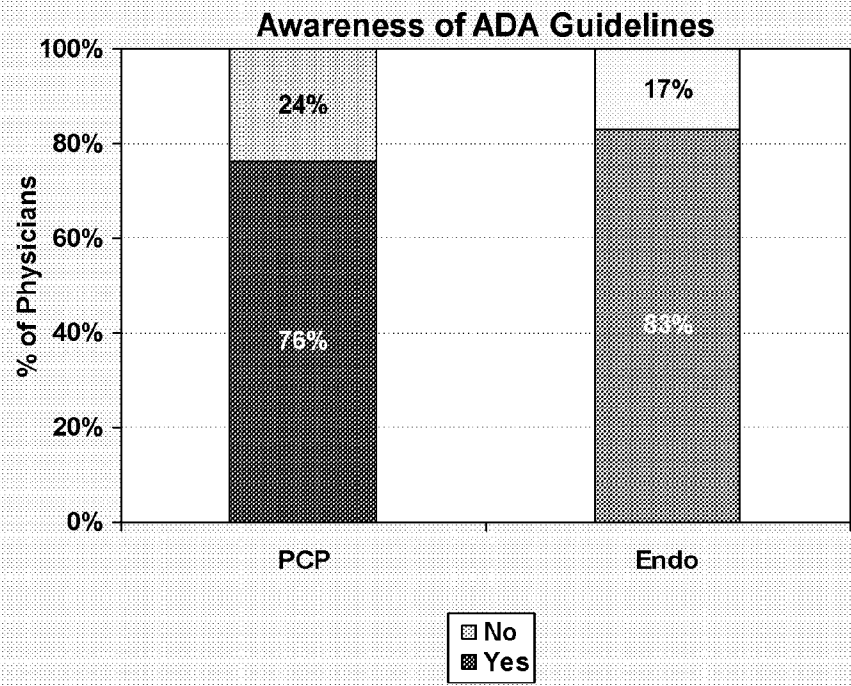




PCPs say they are fairly likely (5.4 on 1 to 7 scale) to initiate insulin sooner as a result of the 2006 ADA guidelines



Awareness of ADA Basal Insulin Initiation Guidelines: by Specialty



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. INS4: Are you aware of the 2006 ADA Guidelines that recommend earlier use of basal insulin among Type 2 patients? INS5: As a result of these guidelines, are you likely to initiate insulin sooner? INS6: How much sooner are you likely to initiate insulin as a result of these guidelines?

Specialty	N
PCP	125
Endo	76

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SANOI13_90330835

PTX-0739.0029
 Sanofi Exhibit 2146.029
 Mylan v. Sanofi
 IPR2018-01675



PCP increases in *adding other insulin options* to their patients uncontrolled on 2 OADs were driven by Premix

	PCP		Endo	
	Mar-Apr '07	Sep-Oct '07	Mar-Apr '07	Sep-Oct '07
	n= 125	n= 125	n= 78	n= 76
Adding other oral agent(s)	37%	27%*	29%	22%
Lantus	25%	26%	20%	25%
Levemir	6%	13%*	10%	10%
Byetta	15%	12%*	23%	18%
Exubera	4%	5%	3%	3%
Premix	7%	10%*	8%	8%
NPH	3%	4%	3%	5%
Other insulin options	3%	3%	4%	7%

COMPASS

Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by patient base. * Statistically different at 95% between Sep-Oct '07 and Mar-Apr '07. LAN5: In your practice over the next year, for Type 2 diabetes patients who are uncontrolled on two oral medications, what percent of the time will you recommend the following?

30

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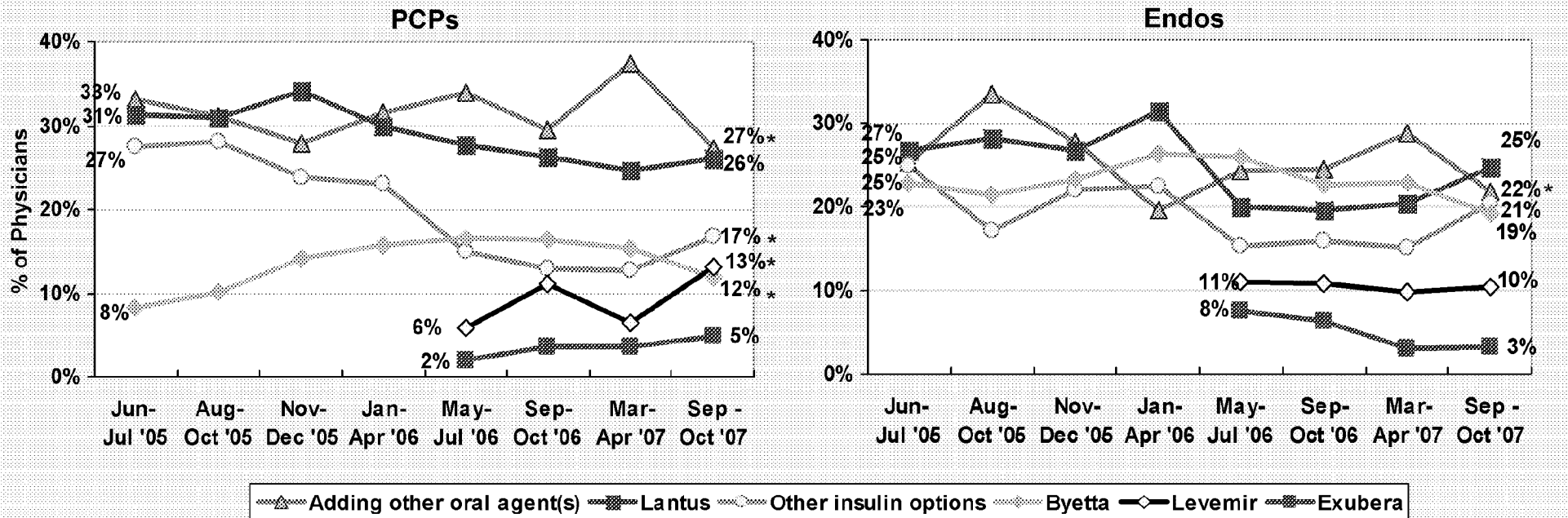
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PTX-0739.0030
 Sanofi Exhibit 2146.030
 Mylan v. Sanofi
 IPR2018-01675



Physicians in Sep-Oct '07 report a significant increase in *adding other insulin options* to their patients uncontrolled on 2 OADs; adding other oral agents decreased, likely due to the emergence of TZD safety risks

Treatments for Type 2 Patients Uncontrolled on Two OADs: by Specialty



Reasons for adding Byetta instead of Lantus

Weight loss / Obesity 73%
 Avoid / Delay Insulinization 6%
 Better for hypoglycemic patients 5%

Reasons for adding Premix instead of Lantus

PPG Control 32%
 Better control (general) 14%
 Minimize injections / ease of use 12%

Reasons for adding Levemir instead of Lantus

Weight neutral 18%
 Sample availability 17%
 Cost / formulary 16%

Note: "Other insulin options" in the charts above are an aggregation of three selections: "Premix", "NPH" and "other insulin options". The increase among PCPs in Sept-Oct '07 is primarily driven by a significant increase in Premix – from 7% to 10%. The increase among Endos, however, was not due to any particular choice - none had statistically significant changes individually.

Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population and patient base. Weighted percent of physicians shown for open-ended questions. Statistical testing between therapies shown in appendix. LAN5: In your practice over the next year, for Type 2 diabetes patients who are uncontrolled on two oral medications, what percent of the time will you recommend the following? LAN10B-D: Why do you initiate some of your patients on [product] instead of Lantus?

Product	Count
LAN5 - PCP	125
LAN5 - Endo	76
LAN 10D	138
LAN10B	110
LAN10C	137





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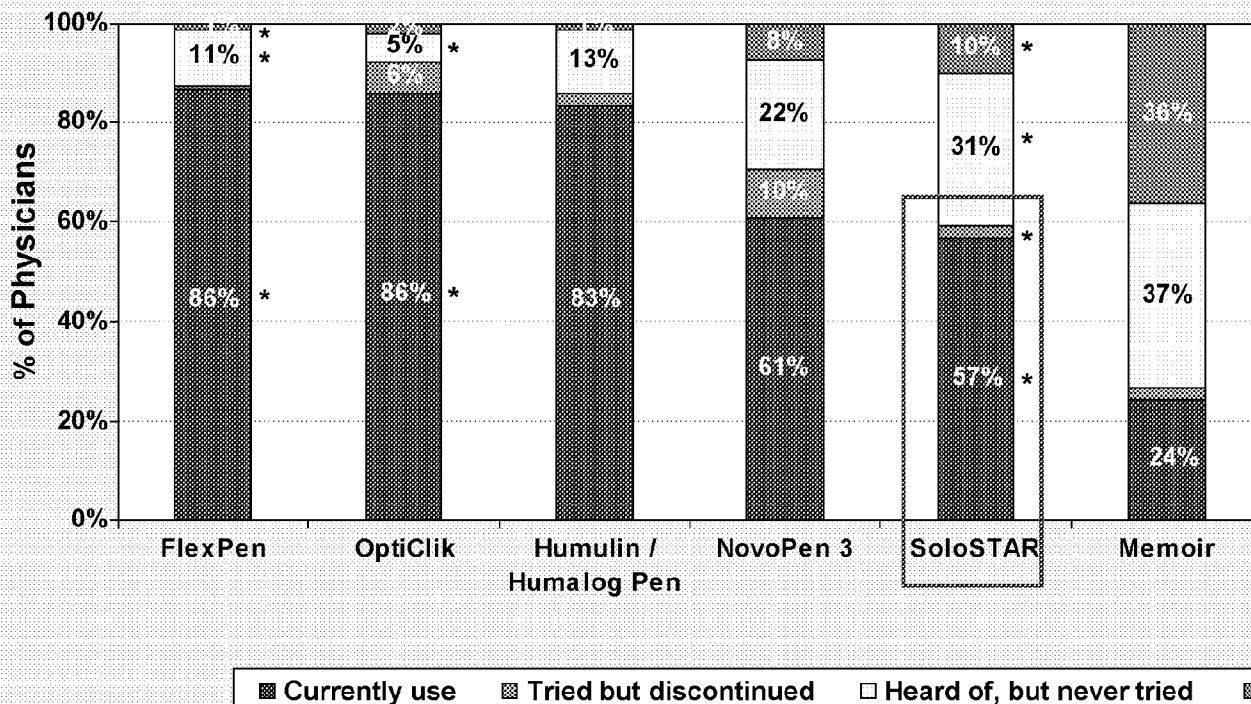
- ◆ Introduction
- ◆ Key Findings
- ◆ Awareness and Trial
- ◆ Special Topics
 - TZD Cardiovascular Safety
 - Awareness/Impact of ADA Guidelines
 - Pen Devices & SoloSTAR
- ◆ Product Perceptions
- ◆ Product Usage
- ◆ Sales Force
- ◆ Appendix



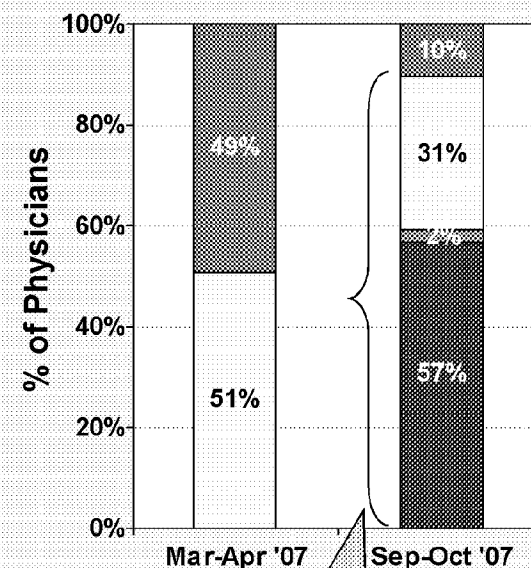
90% of physicians have heard of SoloSTAR; nearly 60% of physicians report currently using SoloSTAR with their patients

Aided Awareness of Pen Devices: Total

Insulin Pen Familiarity: Sep-Oct '07



SoloSTAR Trends

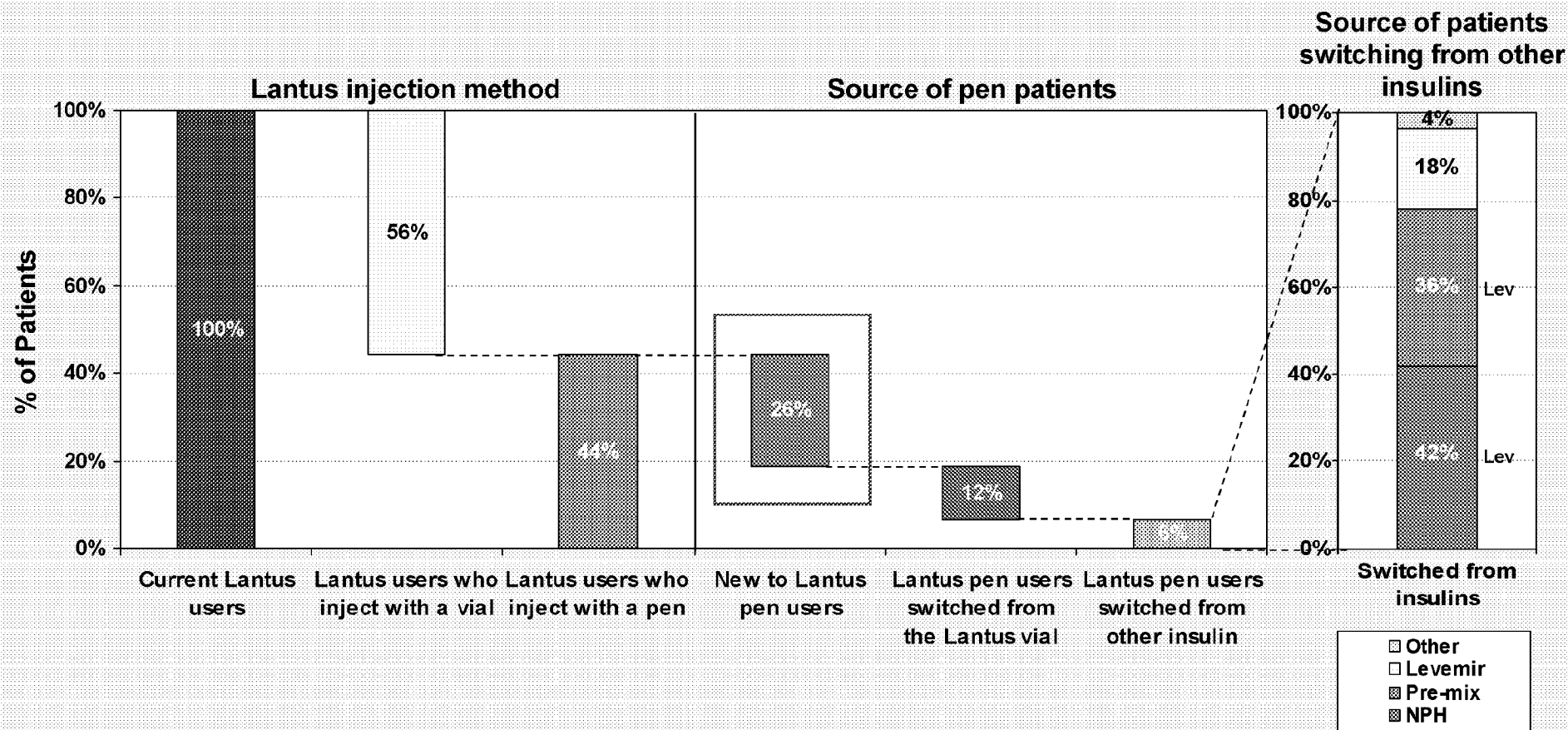


90% of MDs in Sep-Oct '07 report having heard of SoloSTAR



Over one-quarter of Lantus users begin their regimens using a pen device; an additional 18% switch to a Lantus pen after using vials and / or other insulins

Lantus Pen Users and Source of Pen Users: Total



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by patient base and physician population. PEN4A: Of your Type 2 diabetes patients currently using Lantus insulin, what percent of these patients use a vial / syringe and what percent use an insulin pen to inject their Lantus insulin? PEN4B: Of your Type 2 diabetes patients currently using a pen device to inject Lantus insulin, what percent were new to insulin and what percent were switched from the Lantus vial or from another insulin? PEN4C: You indicated that ___% of your Type 2 diabetes patients currently using a pen device to inject Lantus insulin were switched from another insulin. Please allocate this percentage across the following products.

Category	Count
PEN4A	200
PEN4B	186
PEN4C	117

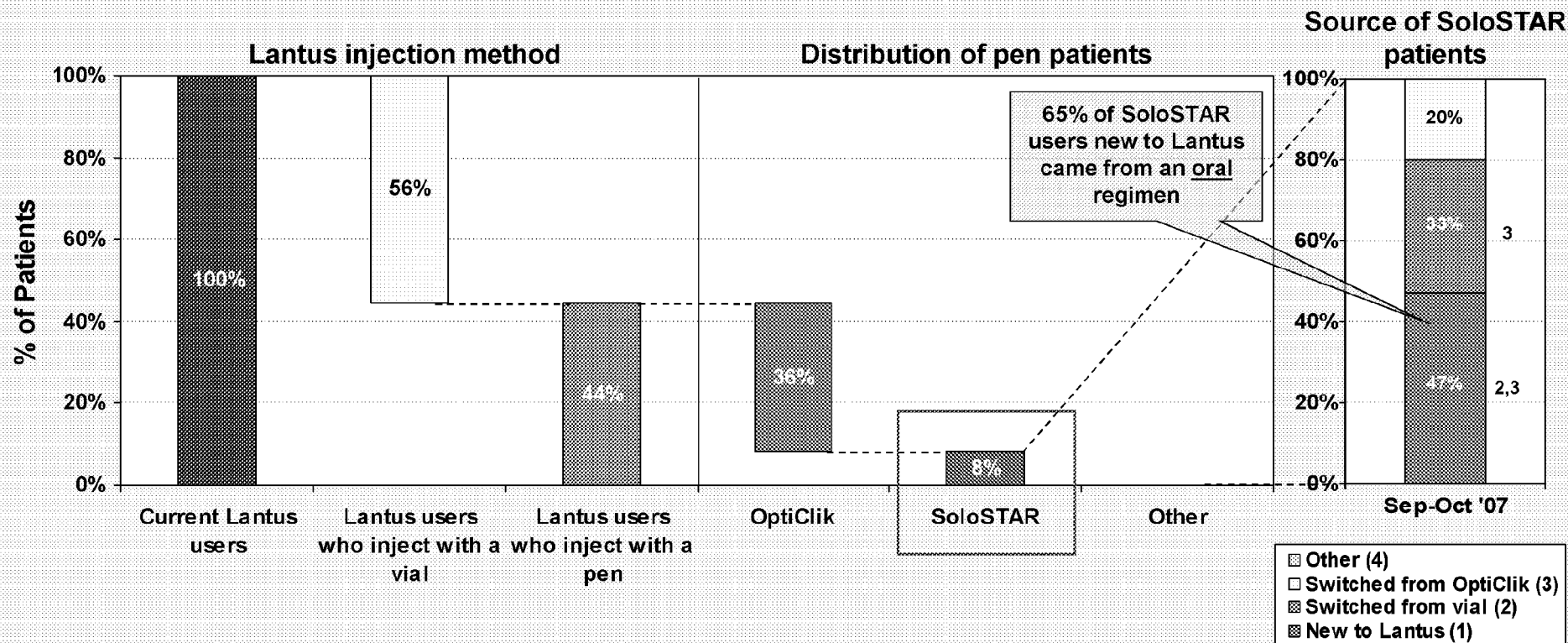
34





In Sep-Oct '07, physicians report that 8% of their Lantus patients inject with the SoloSTAR pen – about half of SoloSTAR users are new to Lantus

Physician Perception of Lantus Pen Users and Source of Pen Users: Total



Note: These perceptual data contrast with actual September 2007 IMS data which shows that only 13% (among total physicians) and 14% (among Lantus Q3-5) of Lantus business (TmL) was for pens.*

*Source: IMS Xponent, and September Monthly MTPC National Report

Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by patient base and physician population. PEN4A: Of your Type 2 diabetes patients currently using Lantus insulin, what percent of these patients use a vial / syringe and what percent use an insulin pen to inject their Lantus insulin? PEN4D:

Of your Type 2 diabetes patients currently using a pen device to inject Lantus insulin, what percent use the following devices? PEN4E: Of your patients who inject Lantus with the SoloSTAR pen device, what percent are new to Lantus, switched from Lantus

vial / syringe, or switched from OptiClik?

PEN4A	200
PEN4D	186
PEN4E	111

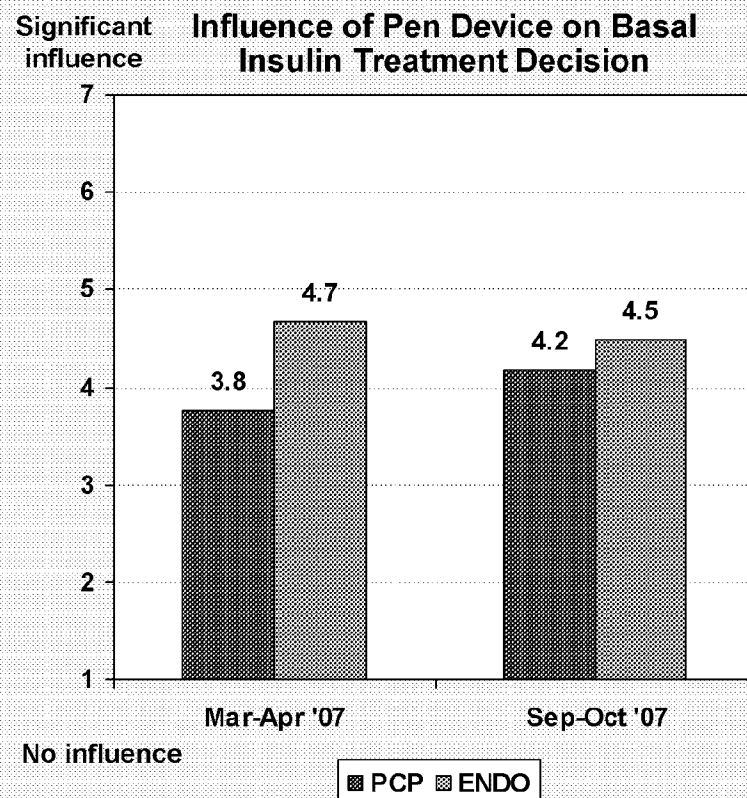
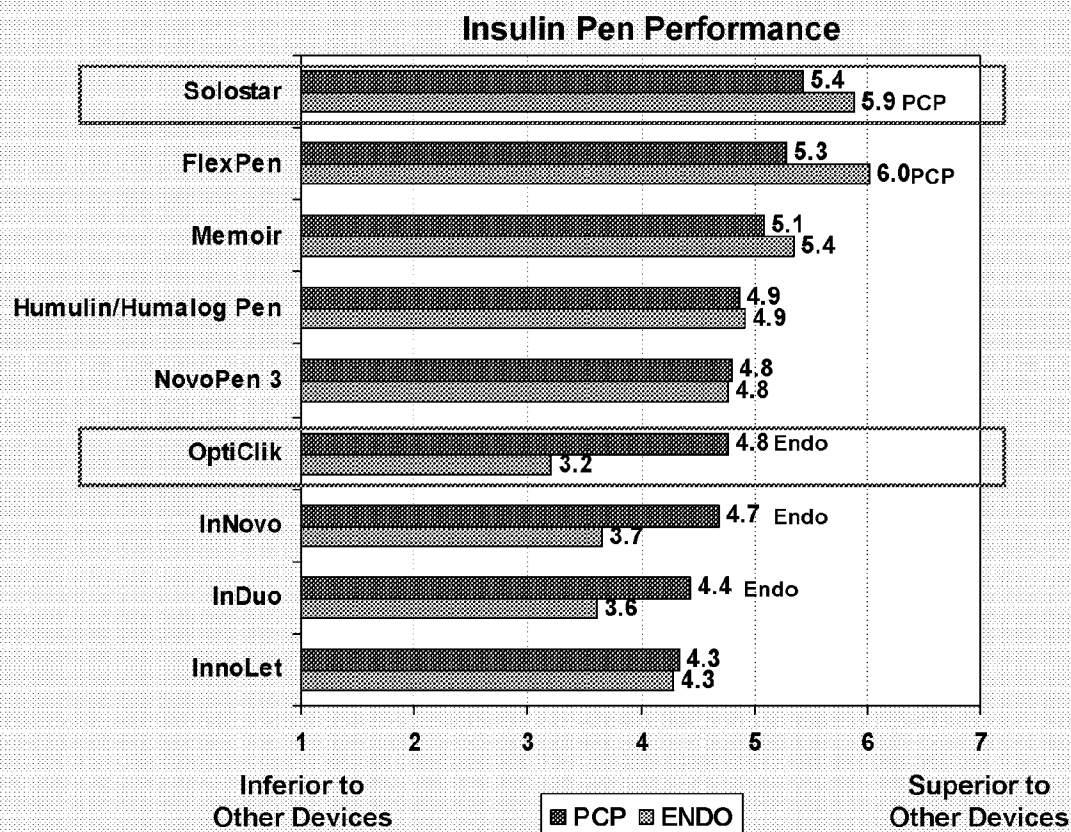
35





Physicians in Sep-Oct '07 rate SoloSTAR as the pen device most superior to other products; pen devices have a moderate influence on basal insulin treatment decisions

Insulin Pen Performance: by Specialty



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population. LAN17: Compared to other pens on the market, how would you rate the following pen devices on a 7 point scale where '1' is 'inferior', '4' is 'no difference' and '7' is superior. LAN36: To what degree does the pen device influence your treatment decision when selecting a basal insulin (Lantus or Levemir)? Please consider the characteristics of the device in your treatment decision.

Sep-Oct '07		
	PCP	Endo
LAN17	31-115	37-75
LAN36	124	76

36



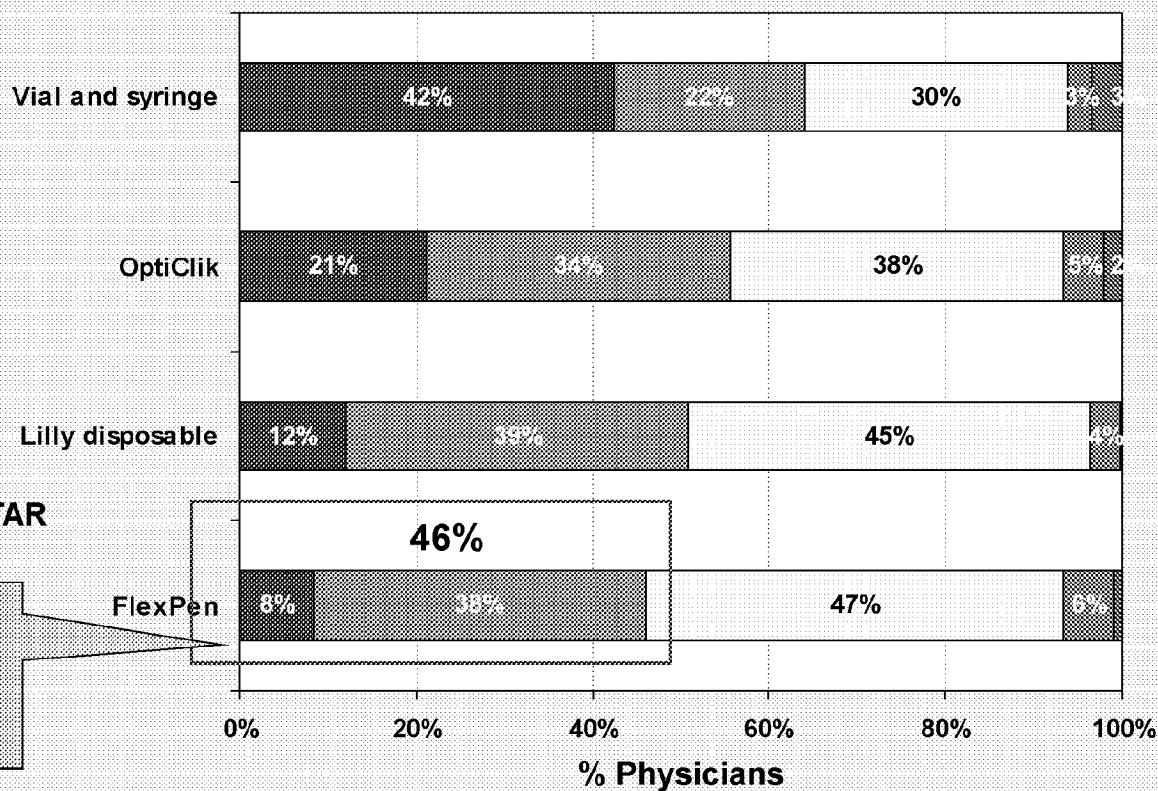


46% of physicians consider SoloSTAR to be either *much better* or *slightly better* than Novo's FlexPen in overall performance

SoloSTAR Comparative Performance Ratings: Total

SoloSTAR is...

Much better than
 Slightly better than
 Equal to
 Slightly worse than
 Much worse than



Reasons for Rating SoloSTAR better than FlexPen:

- 55% Ease of use
- 14% Personal experience
- 11% Less force required
- 6% Patients prefer it
- 6% More insulin per dose



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population. LAN40: Overall, how would you rate SoloSTAR compared to the other insulin injection devices? Please consider the insulin pen independently from the insulin medication it contains. "SoloSTAR is..."

LAN39	187	37
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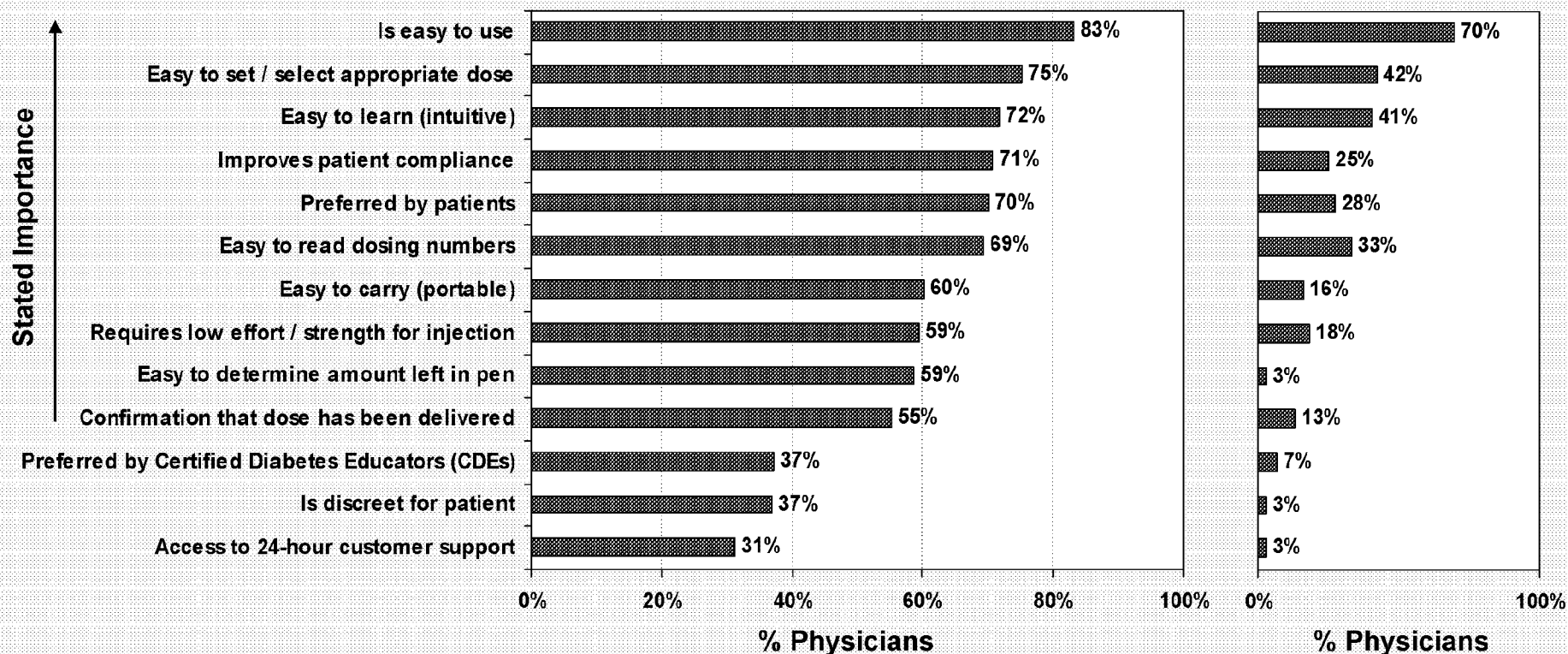


Ease of use and other ease attributes are widely recognized by physicians as the most important factors when considering a diabetes pen

Insulin Pen Attribute Stated Importance: Total

Top 2 Box (Rating 6-7)

Top 3 Most Important Ranking



Source: COMPASS Physician ATU Tracking Study

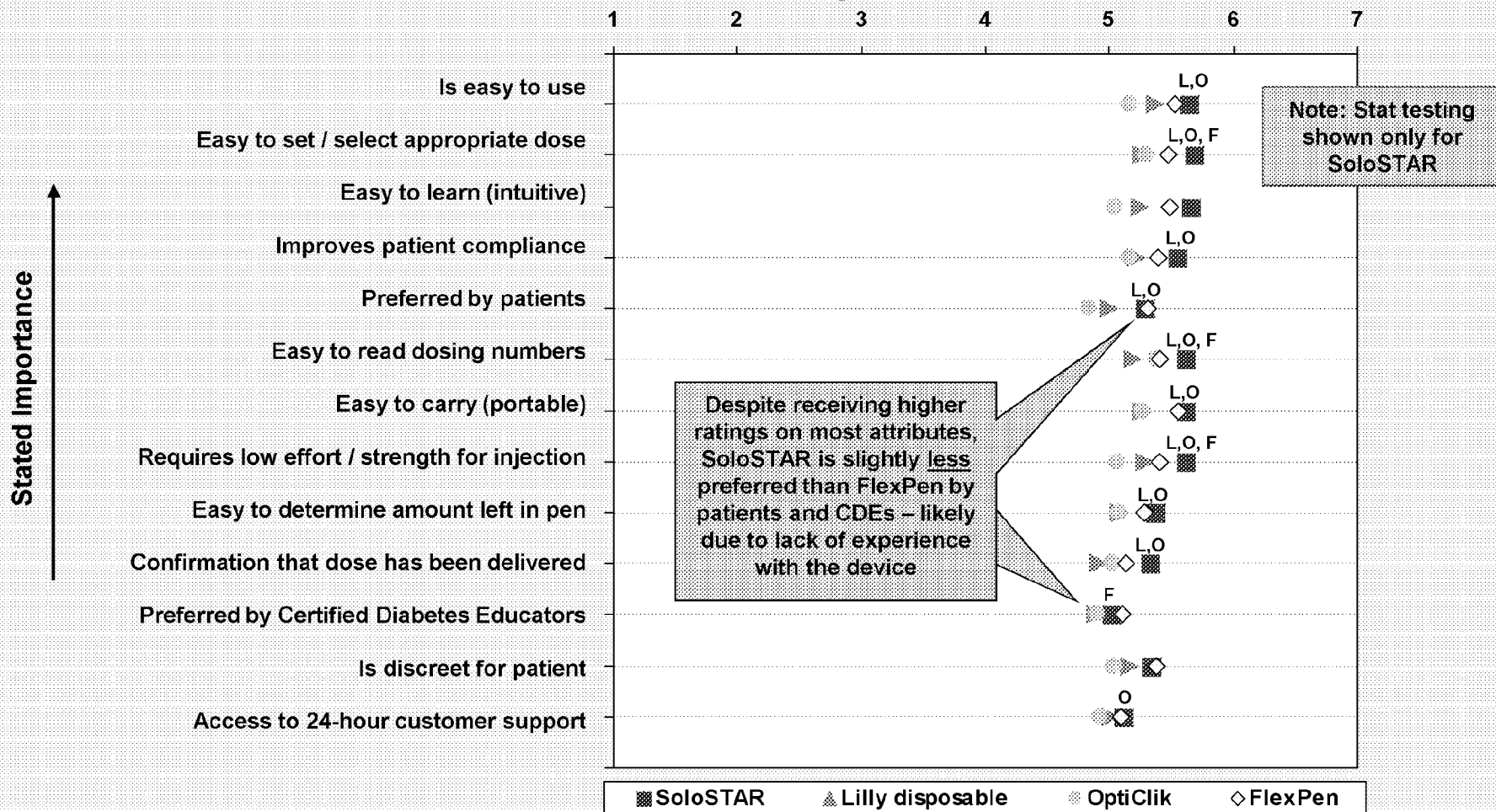
Note: Data are weighted by physician population. LAN37: For each of the factors listed below, please indicate how important each factor is when considering a particular diabetes pen. LAN38: Now, please choose the three attributes which you feel are MOST important when considering a particular diabetes pen.

LAN37	201
LAN38	201



While performance ratings for pen devices are tight, SoloSTAR holds a significant ratings advantage over Lilly disposables and OptiClik on nearly all attributes

Pen Performance Ratings: Total



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population. LAN39: On a scale of 1 to 7, please rate how well you feel each pen performs on these attributes/functions. Use a scale of 1 to 7 where 1 is "Performs Extremely Poorly" and 7 is "Performs Extremely Well".

LAN39	187-201
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Nearly 50% of physicians believe SoloSTAR's ease of use is its primary advantage; cost / formulary status is the most commonly cited disadvantage

SoloSTAR Advantages and Disadvantages: by Specialty

Main Advantages of SoloSTAR

Main Message	Total	PCP	Endo
Easier to use	48%	49%	43%
Easier to read dosage	8%	9%	3%
Less force required	7%	6%	18%
Disposable	5%	5%	5%
Higher insulin capacity	4%	4%	9%
n =	187	111	76

Main Disadvantages of SoloSTAR

Main Message	Total	PCP	Endo
Cost / Formulary status	31%	32%	22%
Lack of experience	6%	6%	1%
Difficult to learn	4%	5%	1%
Bulkiness / Indiscreet	2%	2%	4%
Undifferentiated from others	1%	1%	3%
n =	187	111	76

34% of physicians stated "none" for SoloSTAR's main disadvantages





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Attributes have been grouped into categories to organize the results for presentation purposes

Attribute Organization

Efficacy	
1	Effective at achieving target fasting glucose control
2	Effective in lowering post-prandial glucose
3	Glucose control, as defined by HbA1c levels <7
4	Can control high proportion of patients who are no longer controlled on oral diabetes therapy
5	Provides 24-hour glucose control
6	Effective at preserving beta-cells / slowing disease progression
7	Provides 24-hour glucose control with one daily injection

Safety	
1	Low incidence of nocturnal hypoglycemia
2	Low incidence of symptomatic hypoglycemia
3	High degree of long-term patient compliance
4	Is well tolerated in a majority of patients

Weight	
1	Low degree of weight gain
2	Promotes weight loss
3	Weight-neutral effect

Dosing	
1	Easy to titrate
2	Provides once daily dosing
3	Mimics normal basal insulin release
4	Appropriate for first-time insulin users
5	Low variability in insulin release from day to day in an individual patient
6	Has no unwanted peak

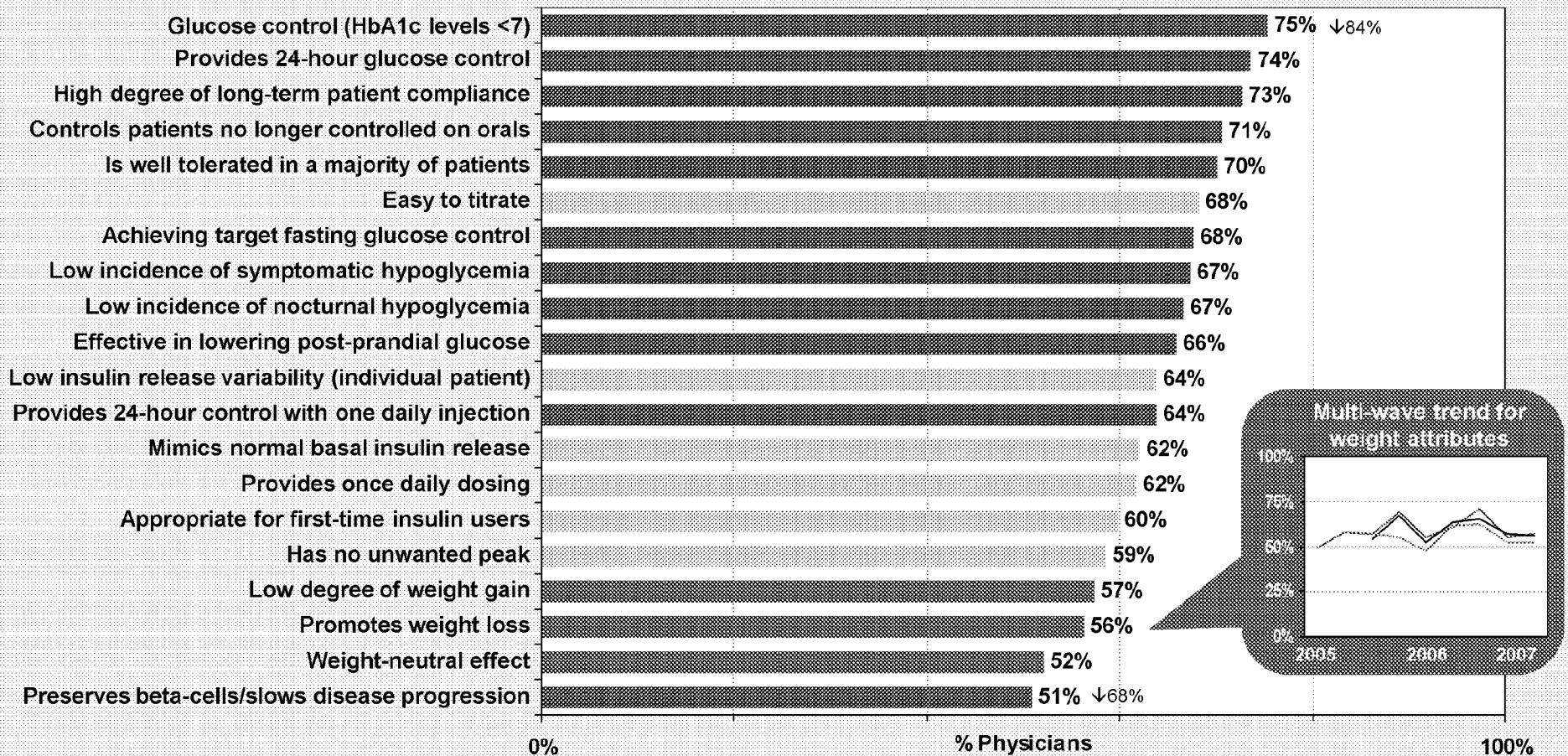




Efficacy and safety attributes are still viewed as most important while weight attributes are considered the least relevant when selecting a diabetes product

Efficacy	Weight
Safety	Dosing

Stated DM Product Attribute Importance Top 2 Box: Total



Source: COMPASS Physician Study
 Note: Data are weighted by physician population. PR3A: For each of the factors listed below, please indicate how important each factor is in your selection of a particular diabetes product for Type 2 patients.

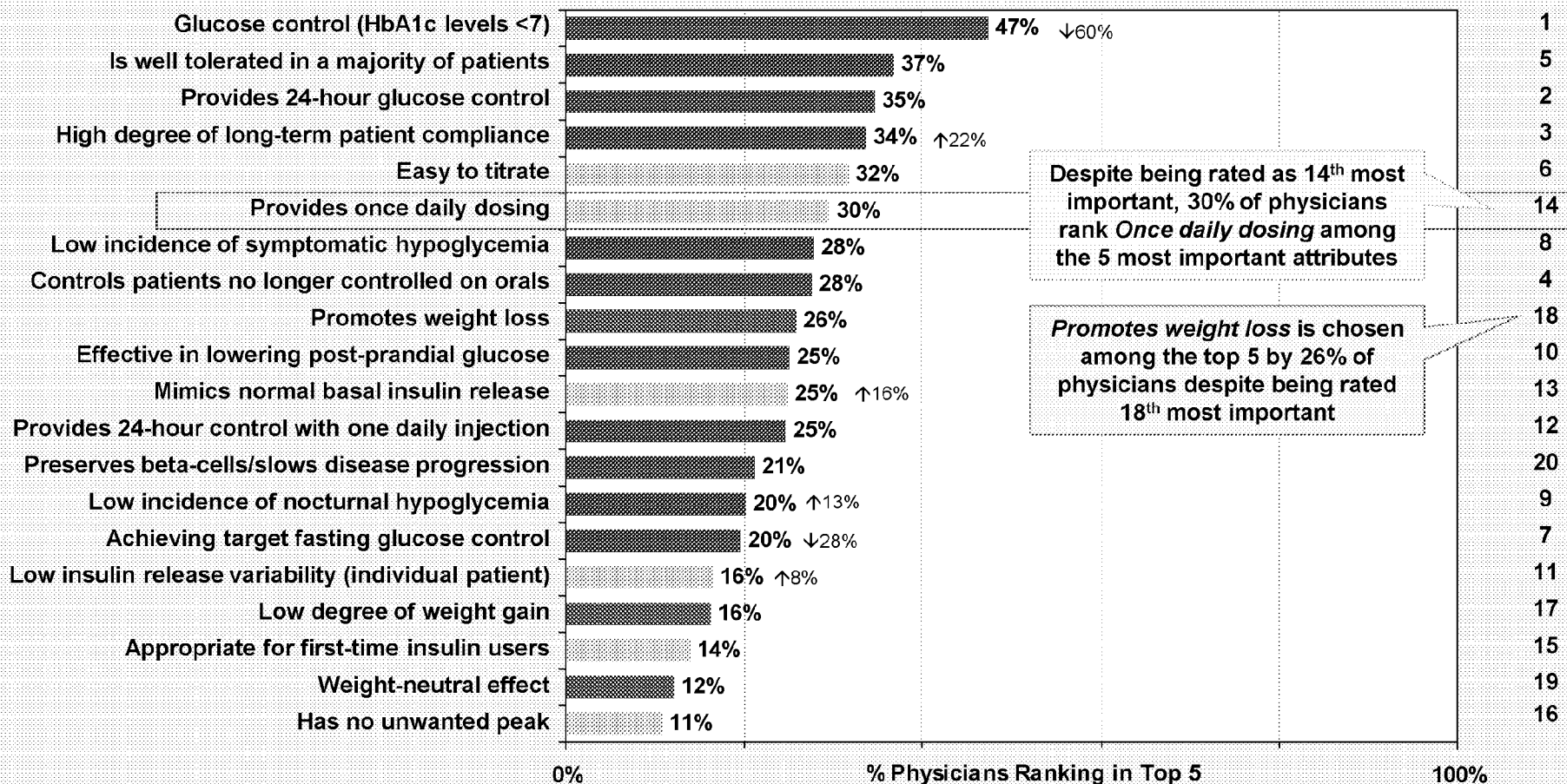


Glucose control (HbA1c levels <7) continues to be ranked among the five most important attributes by the highest percentage of physicians

Efficacy	Weight
Safety	Dosing

Stated DM Product Attribute Importance Top 5 Ranking: Total

Rank based on Top 2 Box Stated Importance RATING



Despite being rated as 14th most important, 30% of physicians rank *Once daily dosing* among the 5 most important attributes

Promotes weight loss is chosen among the top 5 by 26% of physicians despite being rated 18th most important

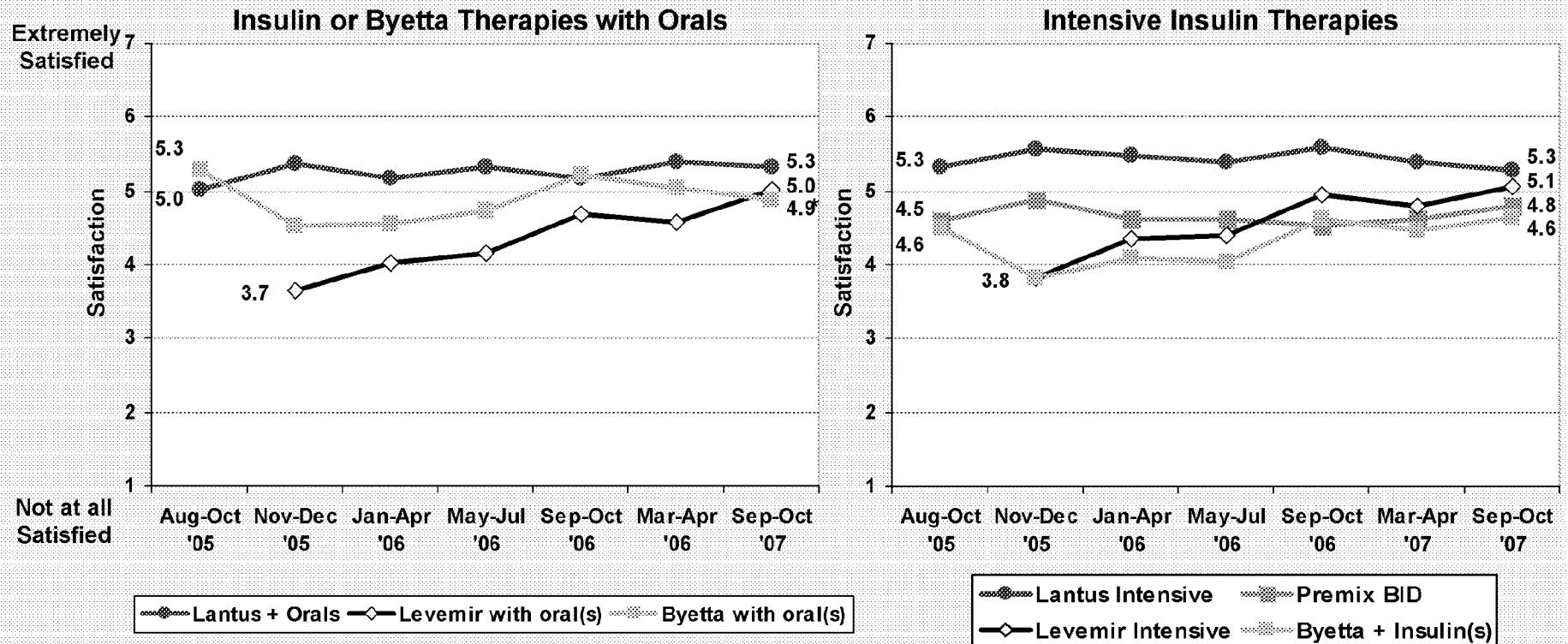


Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by population. PR3A2. Now, please select the five most important factors in your selection of a particular diabetes product for Type 2 patients.



Sep-Oct '07 showed a continued convergence of physicians' overall satisfaction with Lantus and Levemir therapies

Physician Satisfaction Ratings: Total

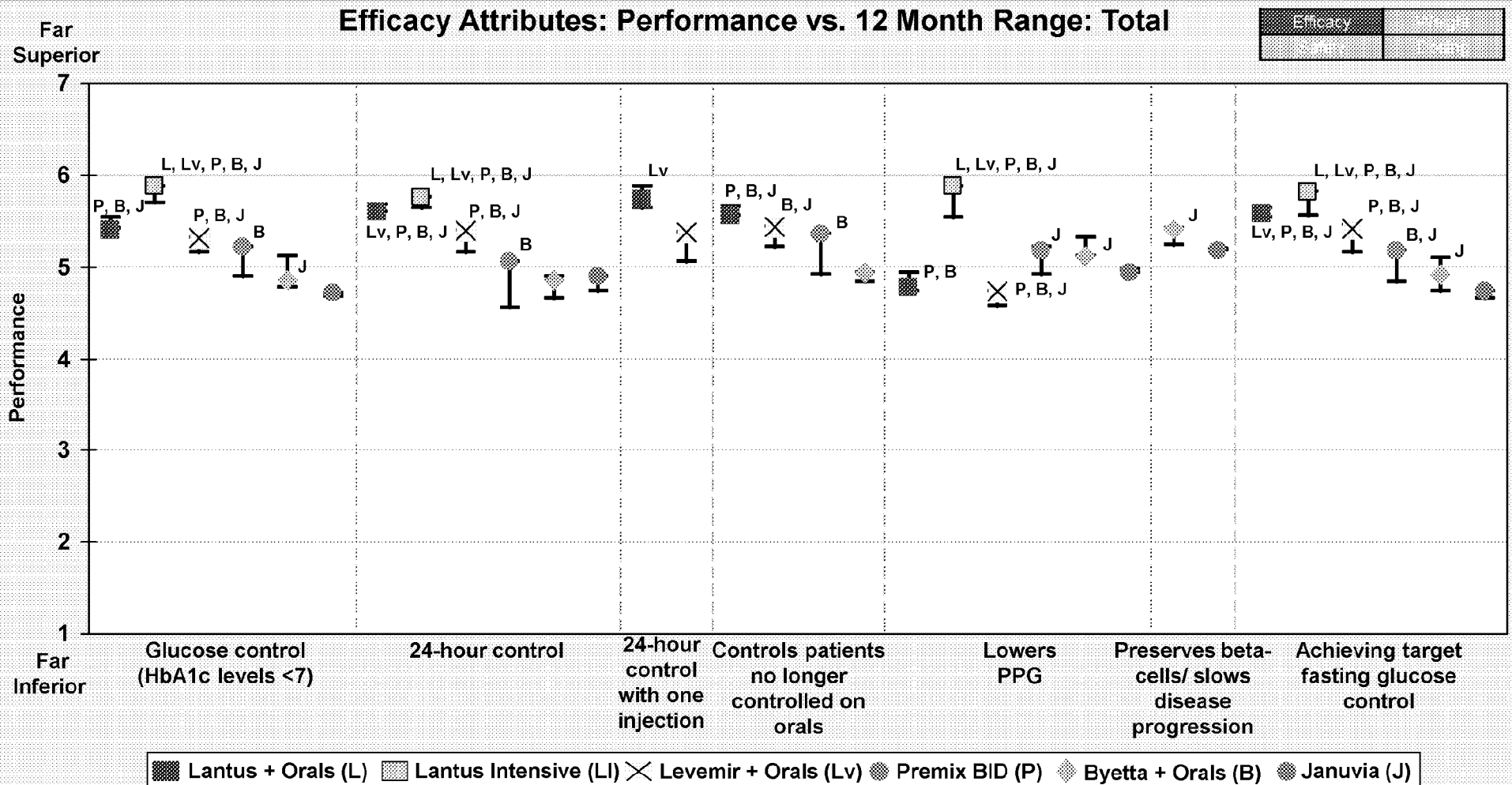


Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. LAN3B: How would you describe your overall satisfaction (efficacy, safety, convenience) provided by each of the following treatment options for diabetes patients, based on your knowledge of and / or experience with the following products?

	Sep-Oct '07	
	n	lt
LAN	201	198
LEV	179	175
PRE	N/A	199
BYT	190	148



Physicians perceive consistent performance on efficacy attributes over the past 12 months for most therapies; however, Premix is at the peak of its performance range



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. Please consider all other therapies that you currently use with your Type 2 diabetes patients (not only the therapies listed below). Not all attributes applicable for all therapies.



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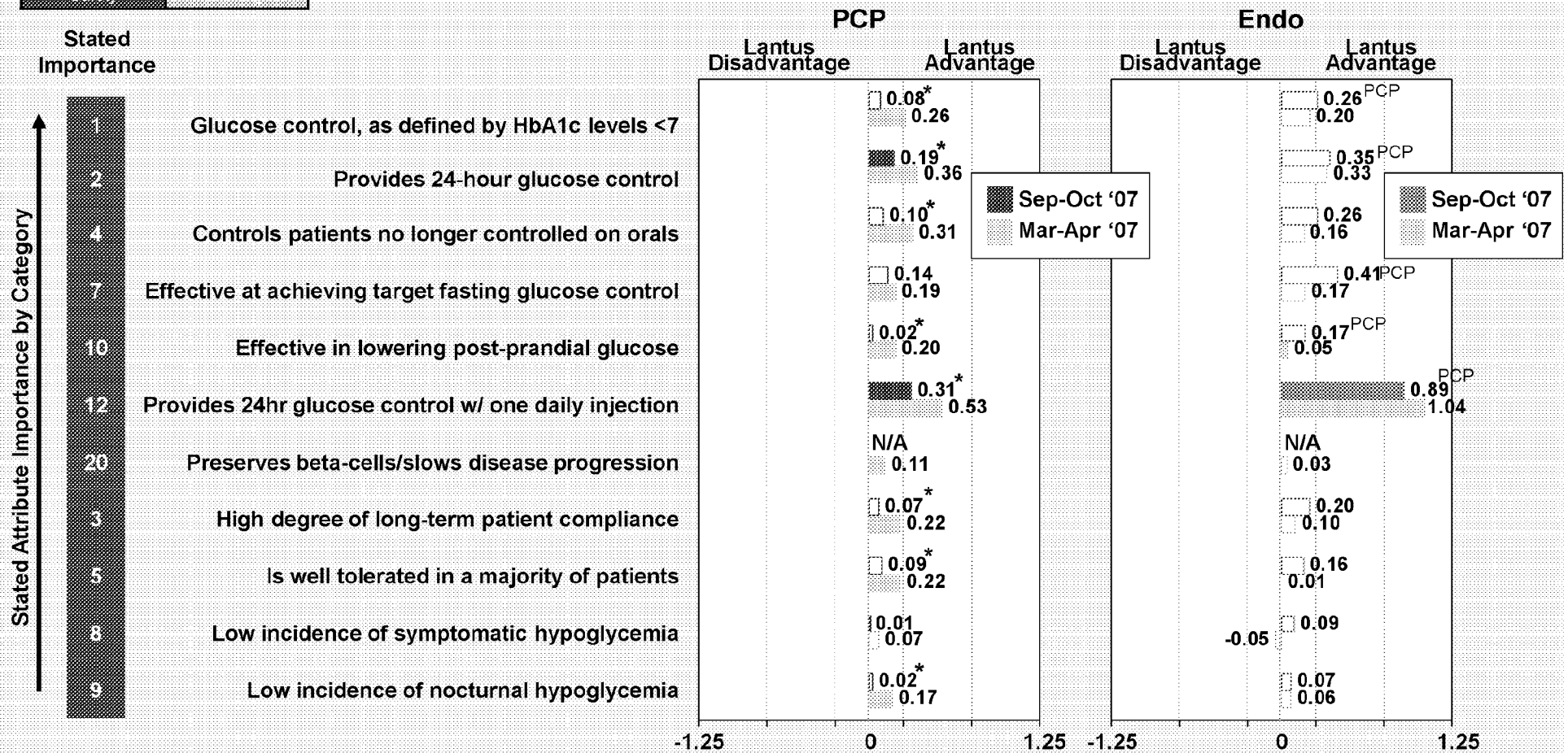




Lantus lost significant ground in its lead over Levemir among PCPs on 8 of 11 efficacy & safety attributes but gained ground directionally with Endos on 9 of them

Efficacy	11
Safety	10

Top Attributes – Lantus with Orals vs. Levemir with Orals: by Specialty



Source: COMPASS Physician ATU Tracking Study
 Notes: Data are weighted by physician population. Statistically different at 95% between products as indicated by filled gaps. Stat testing performed on paired data (physicians who answered for both products). PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. Stated importance rank not calculated by specialty

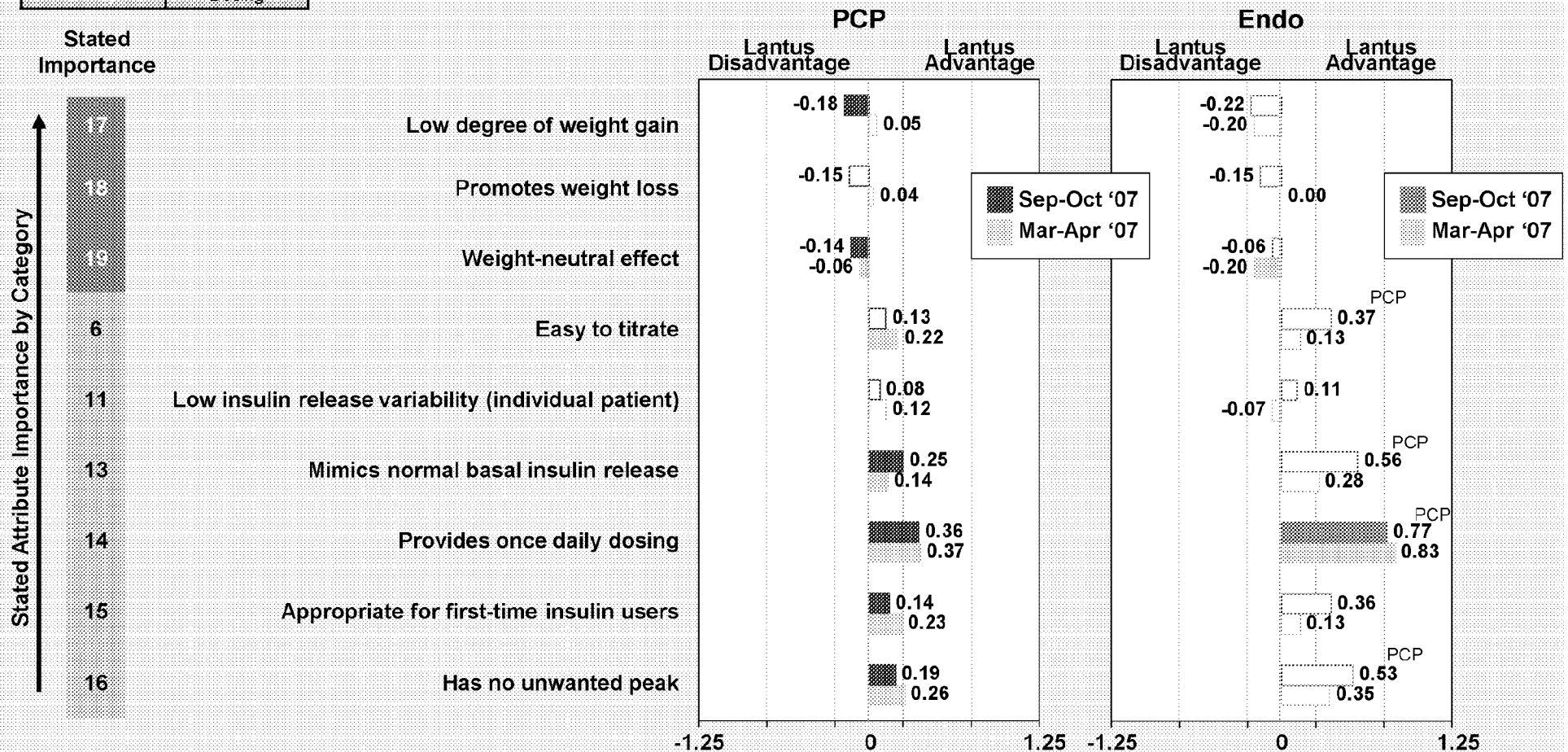
	Sep-Oct '07	PCP	Endo
LAN	125	76	48
LEV	105	74	



Lantus lost ground directionally to Levemir on weight attributes – and is now disadvantaged, but continues to hold an advantage on all dosing related attributes

Effects	Weight
PCP	Dosing

Top Attributes – Lantus with Orals vs. Levemir with Orals: by Specialty



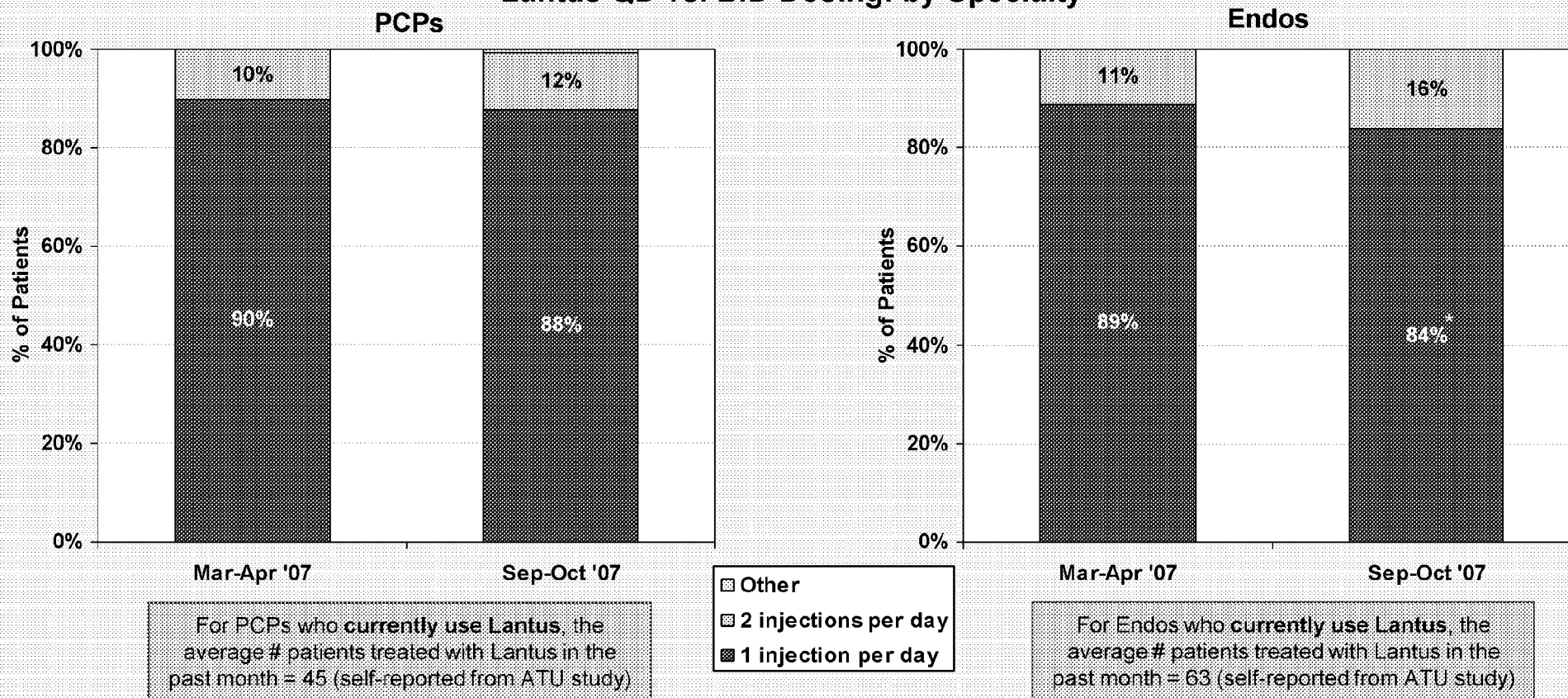
Source: COMPASS Physician ATU Tracking Study
 Notes: Data are weighted by physician population. Statistically different at 95% between products as indicated by filled gaps. Stat testing performed on paired data (physicians who answered for both products). PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. Stated importance rank not calculated by specialty

	Sep-Oct '07	PCP	Endo
LAN	125	76	49
LEV	105	74	



While PCPs report that a similar number of their patients take Lantus once per day in Mar–Apr '07 and Sep–Oct '07, Endos reported a significant decrease in the number of QD Lantus patients

Lantus QD vs. BID Dosing: by Specialty



Source: COMPASS Physician ATU Tracking Study

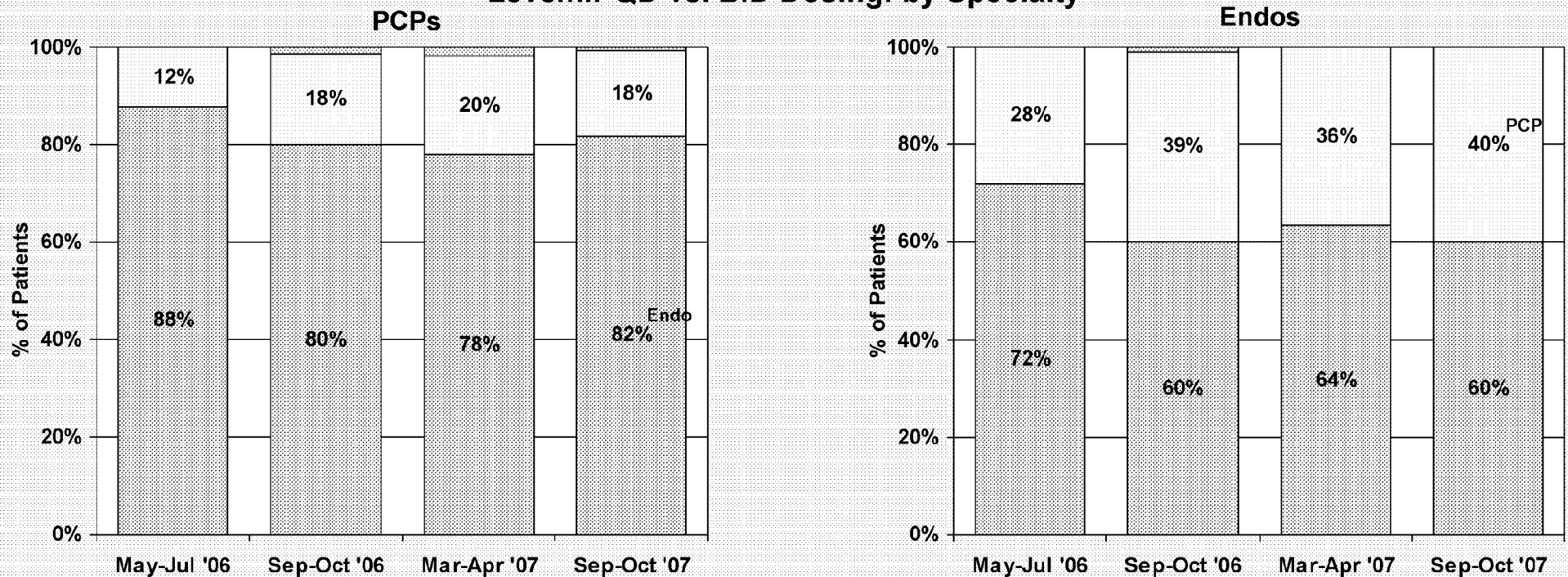
Note: Data are weighted by physician population and patient base. Not statistically different at 95% between specialties. LAN22D: Of your Type 2 diabetes patients who currently use Lantus, what percent of these use Lantus once a day versus twice a day? Average number of patients treated in past month based on Type 2 patient base (BS2A) and self-reported prescribing (BS9_B).

PCP	124
Endo	76



**Perceptions of Levemir dosing have remained stable over the past year
PCPs dose Levemir b.i.d. for 18% of patients, while Endos report 40% of
Levemir use is b.i.d.**

Levemir QD vs. BID Dosing: by Specialty



For PCPs who currently use Levemir, the average # patients treated with Levemir in the past month = 20 (self-reported from ATU study)

- Other
- 2 injections per day
- 1 injection per day

For Endos who currently use Levemir, the average # patients treated with Levemir in the past month = 24 (self-reported from ATU study)



Source: COMPASS Physician ATU Tracking Study

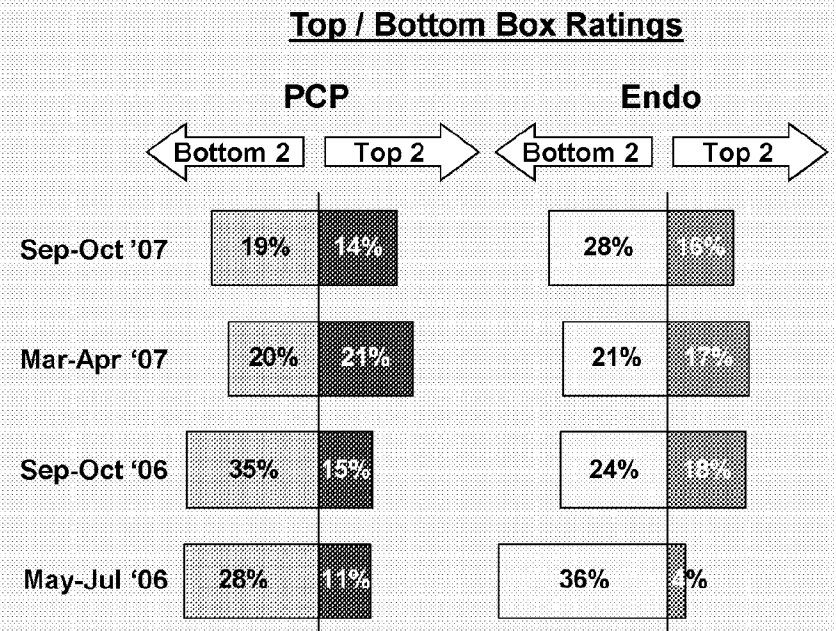
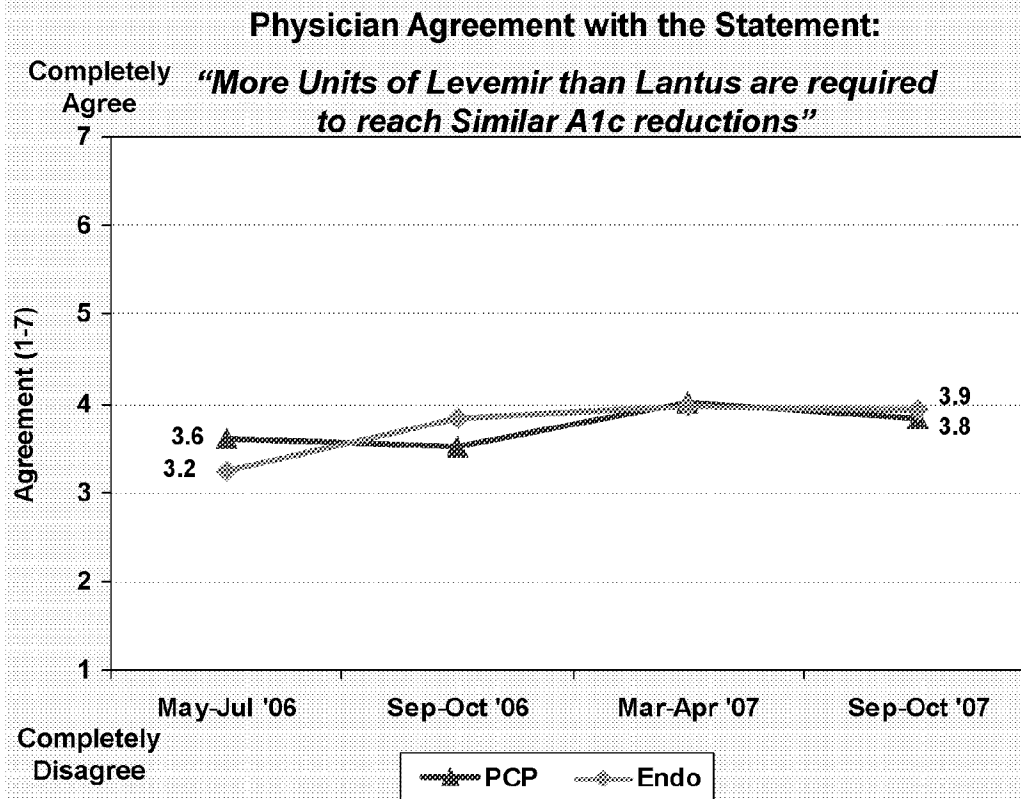
Note: Data are weighted by physician population and patient base. LAN22B. Of your Type 2 diabetes patients who currently use Levemir, what percent of these use Levemir once a day versus twice a day? Average number of patients treated in past month based on Type 2 patient base (BS2A) and self-reported prescribing (BS9_C).

PCP	107
Endo	69



Over the past year, physicians report no major differences in the number of units required to reach similar HbA1c reductions between Lantus and Levemir

Lantus and Levemir Dosing: by Specialty



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. LAN22C: On a scale of 1 to 7, please indicate how much you agree or disagree with the following statement: more units of Levemir than Lantus are required to achieve similar HbA1c reductions in my Type 2 diabetes patients. Question only asked of those physicians who “currently use” Levemir and Lantus.

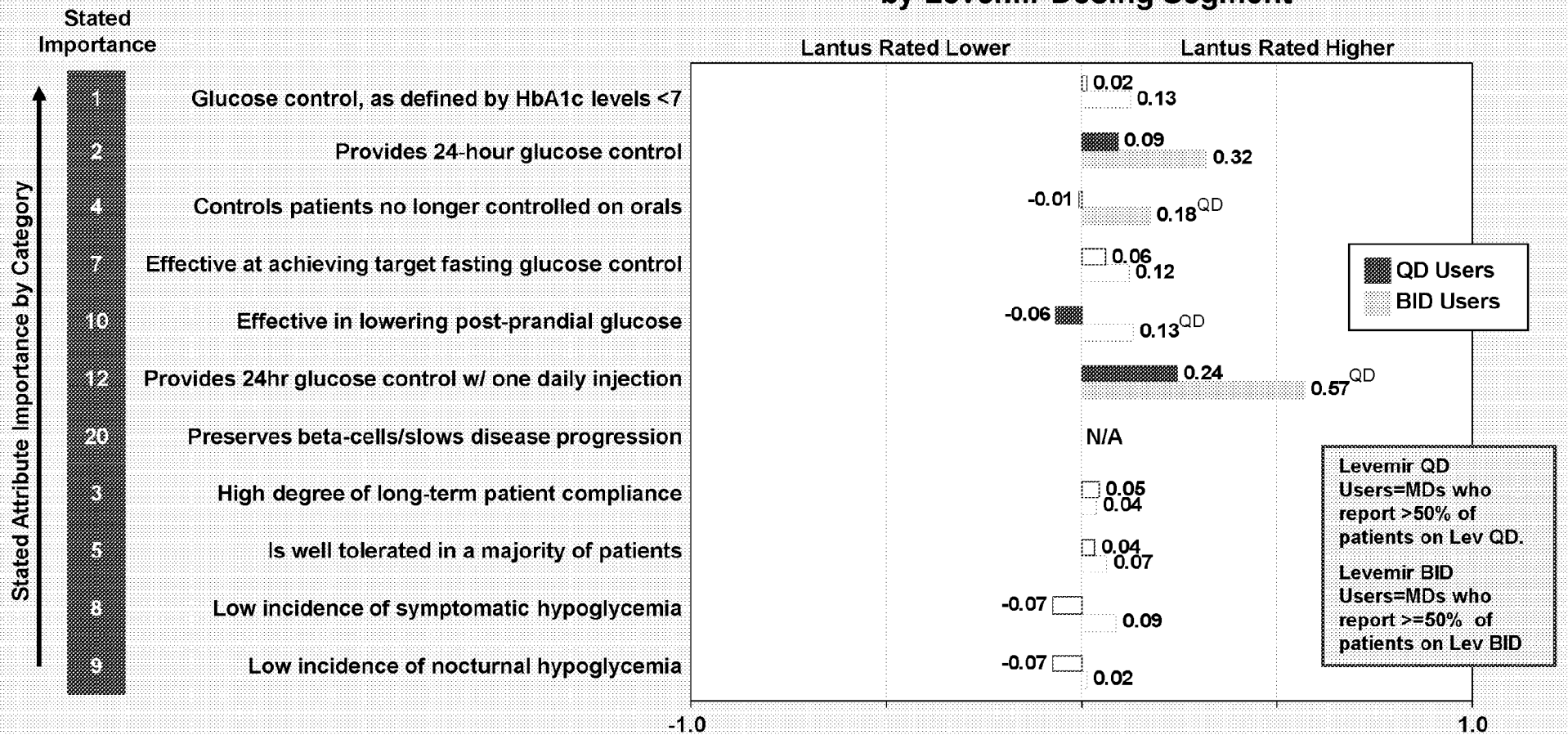
PCP	107
Endo	69



Physicians who use Levemir BID rate Lantus at a higher advantage over Levemir on 9 out of 10 efficacy and safety attributes than those who use it QD

Efficacy	10/10
Safety	9/10

Performance Gaps – Lantus with Orals vs. Levemir with Orals: by Levemir Dosing Segment



Source: COMPASS Physician ATU Tracking Study

Notes: Data are weighted by physician population. Statistically different at 95% between products as indicated by filled gaps. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. LAN22B: Of your Type 2 diabetes patients who currently use Levemir, what percent of these use Levemir once a day versus twice a day?

QD	127
BID	44

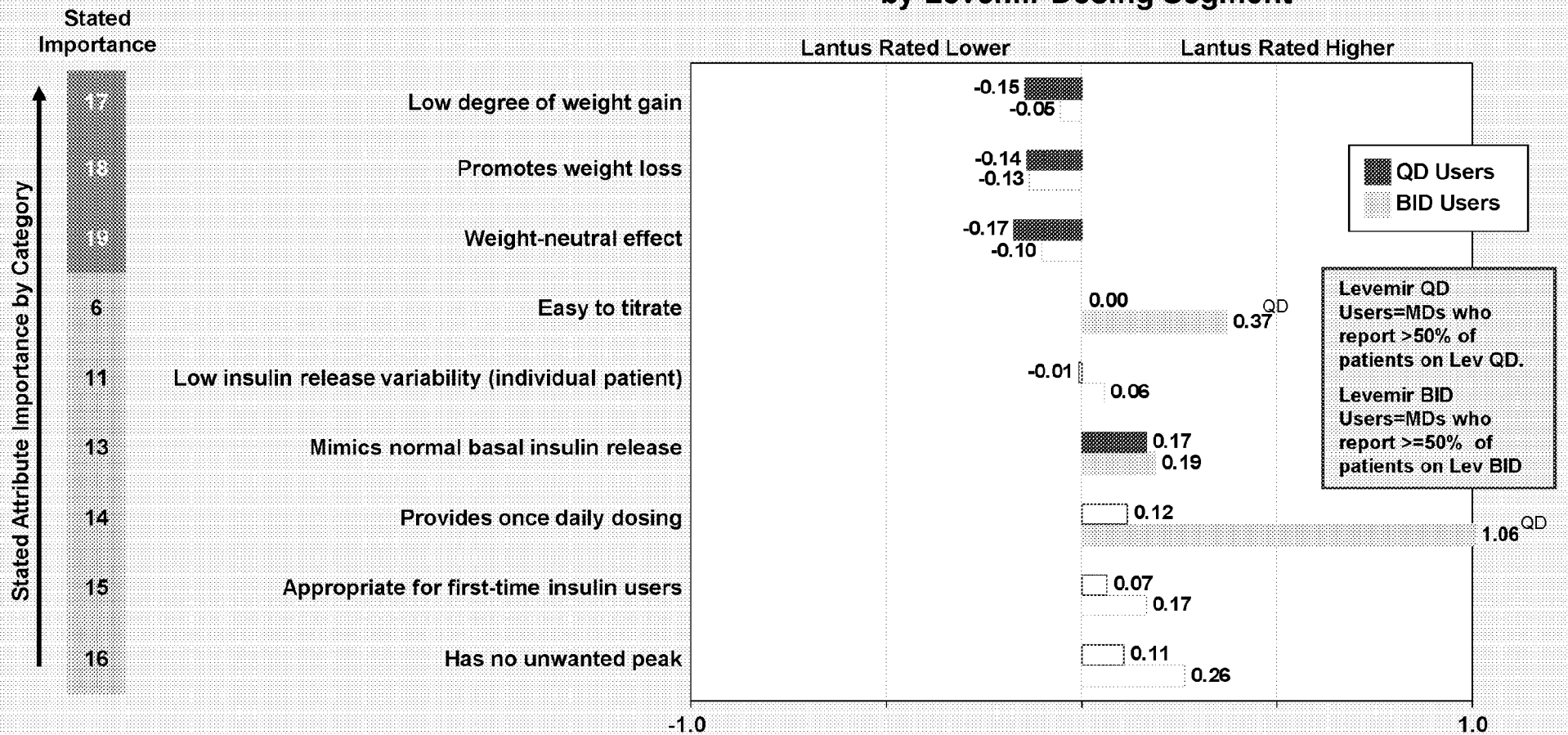




Physicians who use Levemir QD rate it higher than Lantus on weight related attributes, but still rate Lantus at an advantage on most dosing attributes

Effects	Weight
QD	Dosing

Performance Gaps – Lantus with Orals vs. Levemir with Orals: by Levemir Dosing Segment



Source: COMPASS Physician ATU Tracking Study

Notes: Data are weighted by physician population. Statistically different at 95% between products as indicated by filled gaps. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. LAN22B: Of your Type 2 diabetes patients who currently use Levemir, what percent of these use Levemir once a day versus twice a day?

QD	127
BID	44

54

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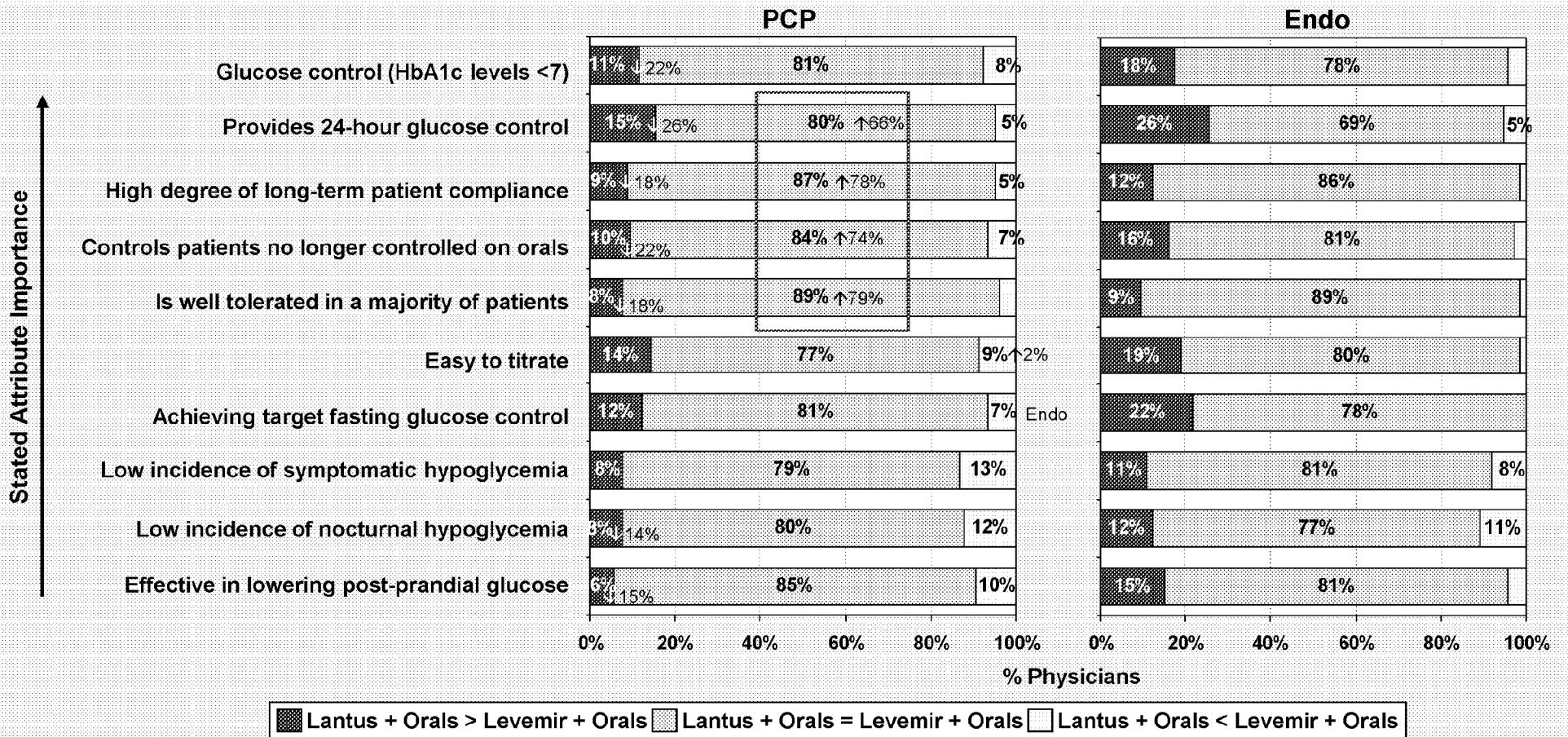
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PTX-0739.0054
 Sanofi Exhibit 2146.054
 Mylan v. Sanofi
 IPR2018-01675



The majority of physicians believe Lantus and Levemir perform similarly on the top 10 attributes; the percentage of PCPs rating Lantus superior to Levemir decreased on several of these attributes since the prior wave

Top 10 Attributes Head-to-Head Performance Ratings: by Specialty
Lantus with Orals vs. Levemir with Orals



Source: COMPASS Physician ATU Tracking Study

Notes: Data are weighted by physician population. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients.

Sample Size	
PCP	105
Endo	74



Unaided, 30% of physicians believe there is little or no difference between Lantus and Levemir

Differences Between Lantus and Levemir: PCP

Biggest Difference, Aside from Pen Devices

Difference	Sep-Oct '06	Mar-Apr '07	Sep-Oct '07
Little / No difference	30%	33%	30%
Duration of action	7%	3%	15%
Less weight gain with Levemir	15%	8%	14%
Cost / Formulary issues	7%	7%	8%
Lantus is QD, Levemir can be BID	15%	16%	5%
n =	108	118	124

Single Greatest Lantus Advantage over Levemir (Excluding Cost / Formulary Status)

Lantus Advantage	Mar-Apr '07	Sep-Oct '07
No Advantage / Same	23%	21%
Experience / familiarity	27%	19%
QD Dosing	12%	18%
n =	82	107

Single Greatest Levemir Advantage over Lantus (Excluding Cost / Formulary Status)

Levemir Advantage	May-Jun '07	Sep-Oct '07
No Advantage / Same	48%	39%
Weight Neutral	12%	16%
Less hypoglycemia	6%	8%
n =	82	107



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by reach. Weighted percent of physicians shown for open-ended questions. LAN19: Aside from differences in pen devices, what do you consider to be the key difference between Lantus and Levemir? LAN10C_A: Excluding cost and formulary status, what do you consider to be the single, greatest advantage of Lantus over Levemir? LAN10C_B: Excluding cost and formulary status, what do you consider to be the single, greatest advantage of Levemir over Lantus?



Unaided, 21% of Endos report QD vs. BID dosing as a major difference between Lantus and Levemir; 38% of physicians mention QD dosing when asked about Lantus' single greatest advantage over Levemir

Differences Between Lantus and Levemir: Endo

Biggest Difference, Aside from Pen Devices

Difference	Sep-Oct '06	Mar-Apr '07	Sep-Oct '07
Duration of action	18%	12%	24%
Lantus is QD, Levemir can be BID	35%	42%	21%
Little / No Difference	11%	10%	18%
Less weight gain with Levemir	18%	10%	16%
Levemir has smoother coverage	2%	4%	9%
n =	55	77	76

QD / BID differences are cited by only 5% of PCPs in Sep-Oct '07

Single Greatest Lantus Advantage over Levemir (Excluding Cost / Formulary Status)

Lantus Advantage	Mar-Apr '07	Sep-Oct '07
QD Dosing	25%	38%
No advantage / Same	16%	17%
Duration of action	16%	16%
n =	75	69

Single Greatest Levemir Advantage over Lantus (Excluding Cost / Formulary Status)

Levemir Advantage	May-Jun '07	Sep-Oct '07
No Advantage / Same	20%	30%
Better pen	37%	16%
Less weight gain	20%	14%
n =	75	69



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by reach. Weighted percent of physicians shown for open-ended questions. LAN19: Aside from differences in pen devices, what do you consider to be the key difference between Lantus and Levemir? LAN10C_A: Excluding cost and formulary status, what do you consider to be the single, greatest advantage of Lantus over Levemir? LAN10C_B: Excluding cost and formulary status, what do you consider to be the single, greatest advantage of Levemir over Lantus?



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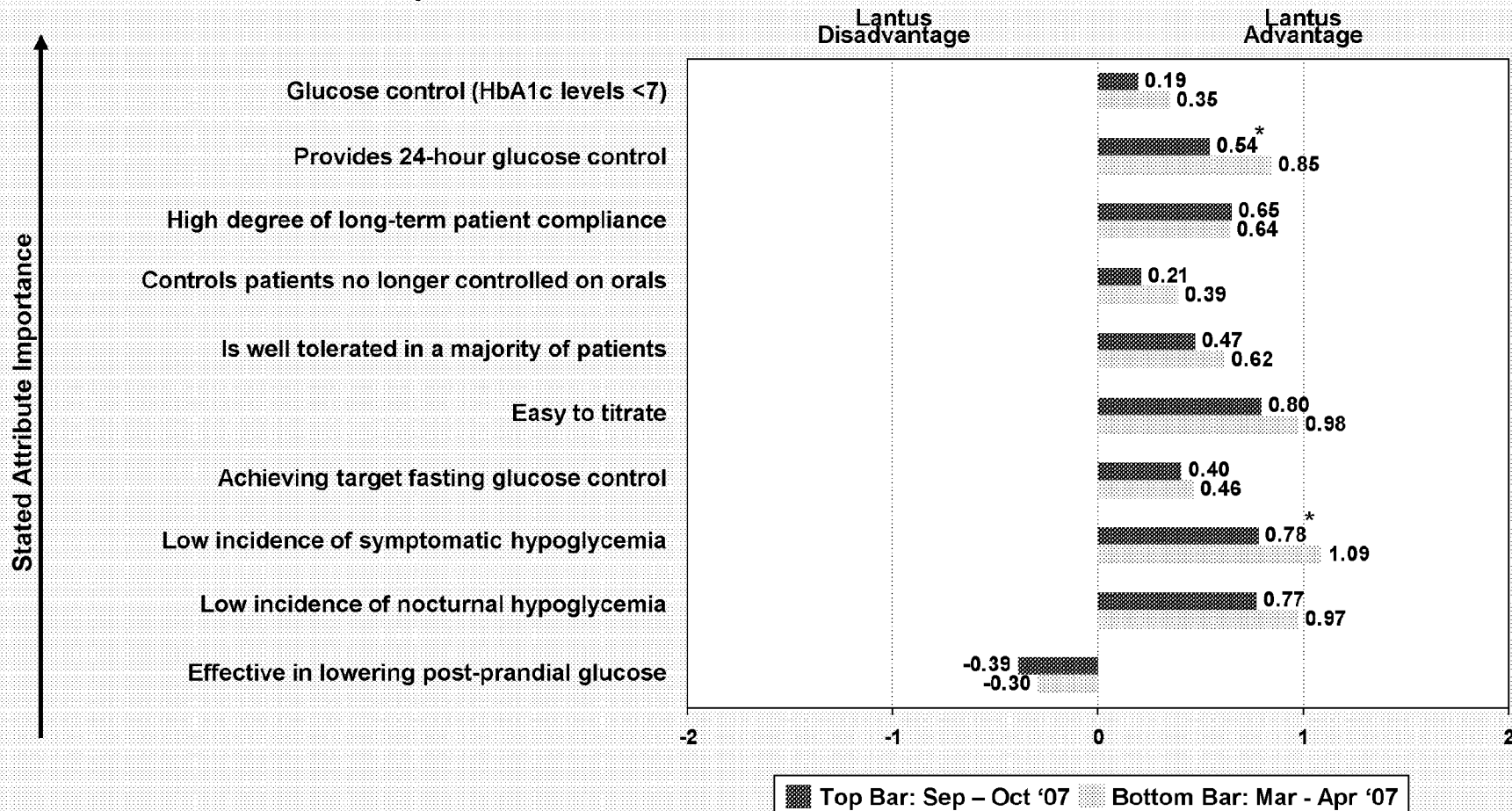
- ◆ Introduction
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 - Lantus vs. Levemir
 - Lantus vs. Premix and Byetta
 - Message Association
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Pre-mix BID continues to erode Lantus' advantage on several of the top 10 attributes, especially on 24 hour glucose control and low incidence of symptomatic hypoglycemia

Top 10 Attributes – Lantus with Orals vs. Premix BID: Total



Source: COMPASS Physician ATU Tracking Study

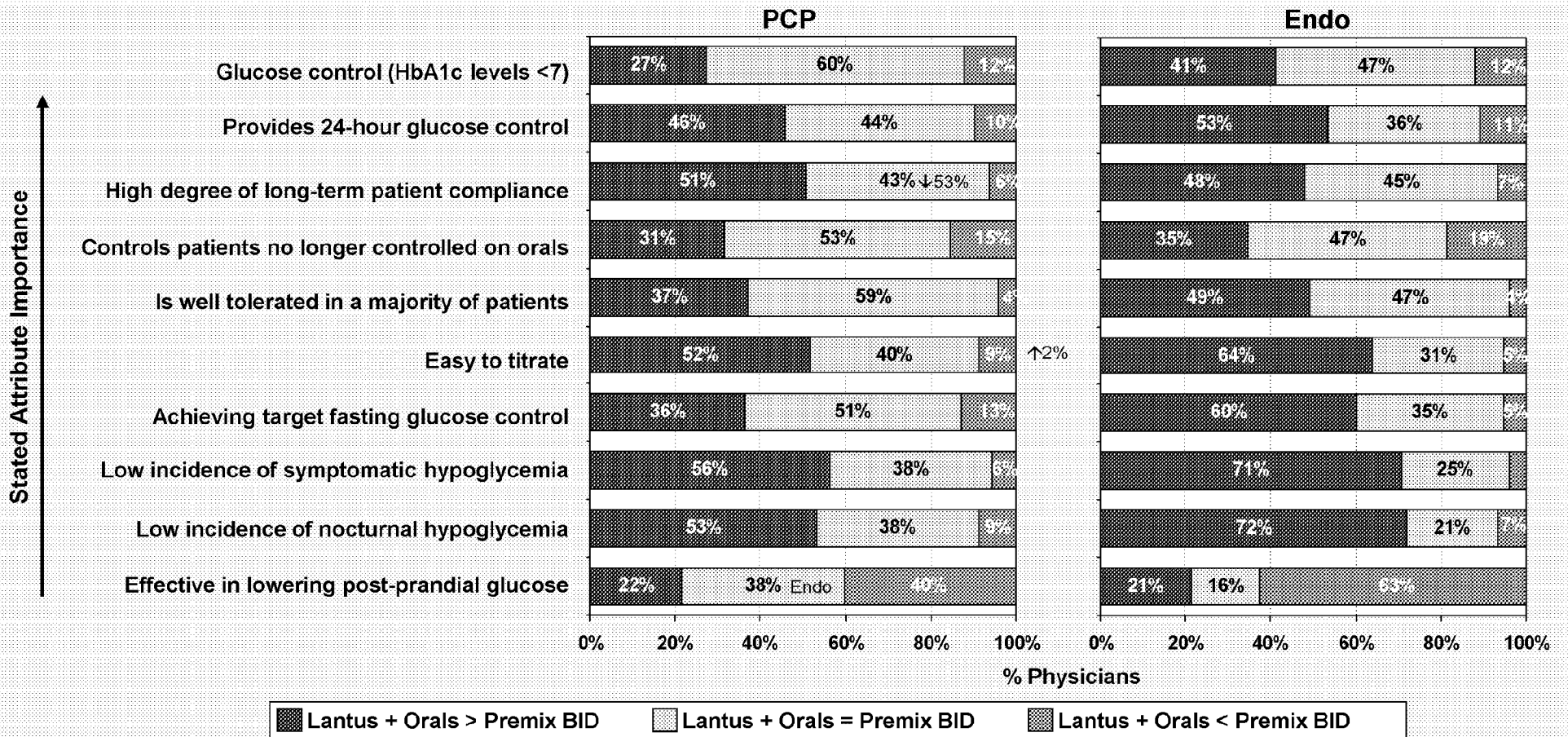
Notes: Data are weighted by physician population. Statistically different at 95% between products as indicated by filled gaps. Stat testing performed on paired data (physicians who answered for both products). PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients.

LAN	201
PRE	199



Physicians perceive Lantus with Orals to be equivalent or superior to Premix BID across the top 10 attributes with the exception of *effective in lowering PPG*

Top 10 Attributes Head-to-Head Performance Ratings: by Specialty
Lantus with Orals vs. Premix BID



Source: COMPASS Physician ATU Tracking Study

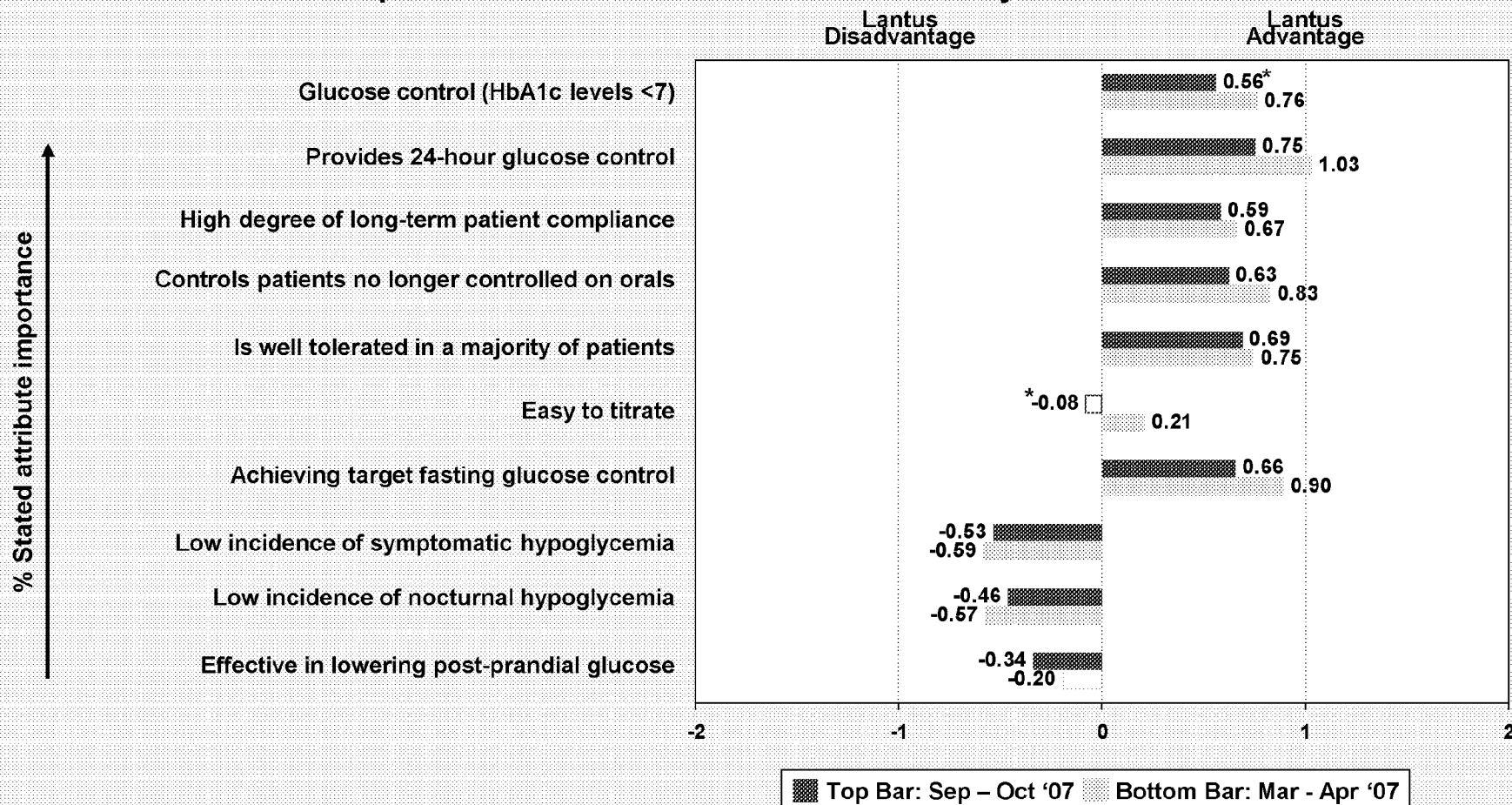
Notes: Data are weighted by physician population. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients.

Specialty	
PCP	124
Endo	75



Lantus' performance advantage over Byetta on *glucose control* attributes remains strong in Sep-Oct '07

Top 10 Attributes – Lantus with Orals vs. Byetta with Orals: Total



Source: COMPASS Physician ATU Tracking Study

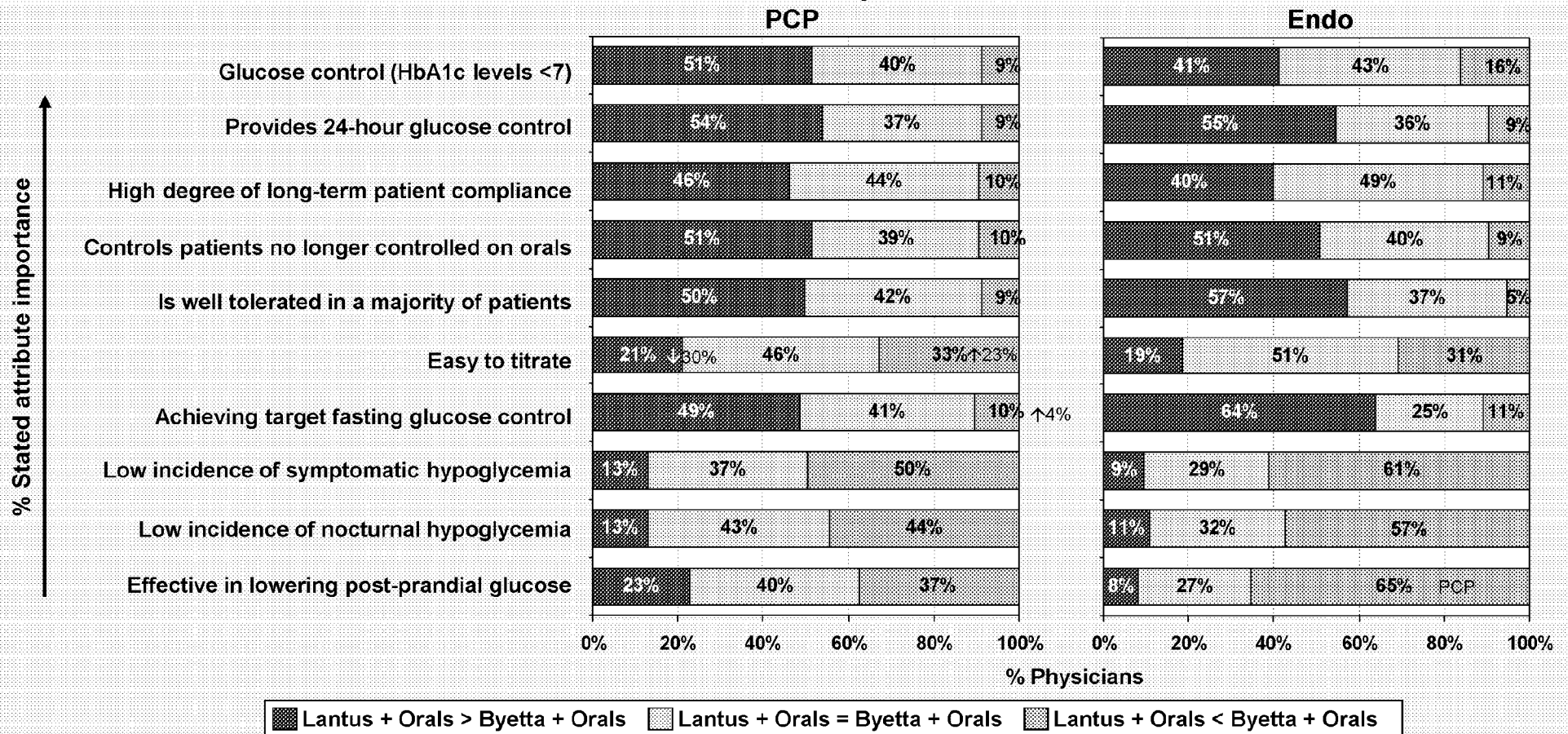
Notes: Data are weighted by physician population. Statistically different at 95% between products as indicated by filled gaps. Stat testing performed on paired data (physicians who answered for both products). PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients.

LAN	201
BYT	190



Roughly 50% of physicians perceive Lantus with Orals as superior to Byetta with Orals on efficacy attributes

Top 10 Attributes Head-to-Head Performance Ratings: by Specialty
Lantus with Orals vs. Byetta with Orals



Source: COMPASS Physician ATU Tracking Study

Notes: Data are weighted by physician population. Statistically different at 95% between products as indicated by filled gaps. Stat testing performed on paired data (physicians who answered for both products). PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients.

PCP	115
Endo	75



DM Product Attribute Scorecard Lantus vs. Key Competitors Mean Ratings

Efficacy	Weight
Safety	Dosing

	Lantus is inferior
	Lantus is undifferentiated
	Lantus is superior
	Significant increase / decrease in gap vs. prior wave

Gap Trend: Lantus minus Competitor

Stated Importance	Attribute	LEV	BYT	PRE	JAN
1	Glucose control, as defined by HbA1c levels <7	▼	▼		
2	Provides 24-hour glucose control	▼		▼	
4	Controls patients no longer controlled on orals	▼			N/A
7	Effective at achieving target fasting glucose control				
10	Effective in lowering post-prandial glucose	▼			
12	Provides 24-hour glucose control with one daily injection	▼	N/A	N/A	N/A
20	Effective at preserving beta-cells / slowing disease progression	N/A	N/A	N/A	N/A
3	High degree of long-term patient compliance	▼			
5	Is well tolerated in a majority of patients	▼			
8	Low incidence of symptomatic hypoglycemia			▼	
9	Low incidence of nocturnal hypoglycemia	▼			
17	Low degree of weight gain	▼			
18	Promotes weight loss				
18	Weight-neutral effect				▼
6	Easy to titrate	▼	▼		N/A
11	Low insulin release variability (in an individual patient)		N/A		N/A
13	Mimics normal basal insulin release		N/A		N/A
14	Provides once daily dosing			N/A	
15	Appropriate for first-time insulin users		N/A		N/A
16	Has no unwanted peak		N/A	▼	N/A

LAN	201
LEV	179
BYT	190
PRE	199
JAN	191



Source: COMPASS Physician ATU Tracking Study

Note: Data are weighted by physician population. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. Please consider all other therapies that you currently use with your Type 2 diabetes patients (not only the therapies listed below). Not all attributes applicable for all therapies.

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PTX-0739.0063
Sanofi Exhibit 2146.063
Mylan v. Sanofi
IPR2018-01675



DM Product Attribute Scorecard Lantus vs. Levemir Mean Ratings – by Specialty

Efficacy	Weight
Safety	Dosing

	Lantus is inferior
	Lantus is undifferentiated
	Lantus is superior
	Significant increase / decrease in gap vs. prior wave

Stated Importance	Attribute	Gap Trend: Lantus minus Levemir		
		Total	PCP	Endo
1	Glucose control, as defined by HbA1c levels <7	▼	▼	PCP
2	Provides 24-hour glucose control	▼	▼	PCP
4	Controls patients no longer controlled on orals	▼	▼	
7	Effective at achieving target fasting glucose control			PCP
10	Effective in lowering post-prandial glucose	▼	▼	PCP
12	Provides 24-hour glucose control with one daily injection	▼	▼	PCP
20	Effective at preserving beta-cells / slowing disease progression	N/A	N/A	
3	High degree of long-term patient compliance	▼	▼	
5	Is well tolerated in a majority of patients	▼	▼	
8	Low incidence of symptomatic hypoglycemia			
9	Low incidence of nocturnal hypoglycemia	▼	▼	
17	Low degree of weight gain	▼		
18	Promotes weight loss			
19	Weight-neutral effect			
6	Easy to titrate	▼		PCP
11	Low insulin release variability (in an individual patient)			
13	Mimics normal basal insulin release			PCP
14	Provides once daily dosing			PCP
15	Appropriate for first-time insulin users			
16	Has no unwanted peak			PCP



Source: COMPASS Physician ATU Tracking Study.
 Note: Data are weighted by physician population. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. Statistically different at 95% between specialties as noted. PCP = gap larger than PCP gap. Please consider all other therapies that you currently use with your Type 2 diabetes patients (not only the therapies listed below). Not all attributes applicable for all therapies.

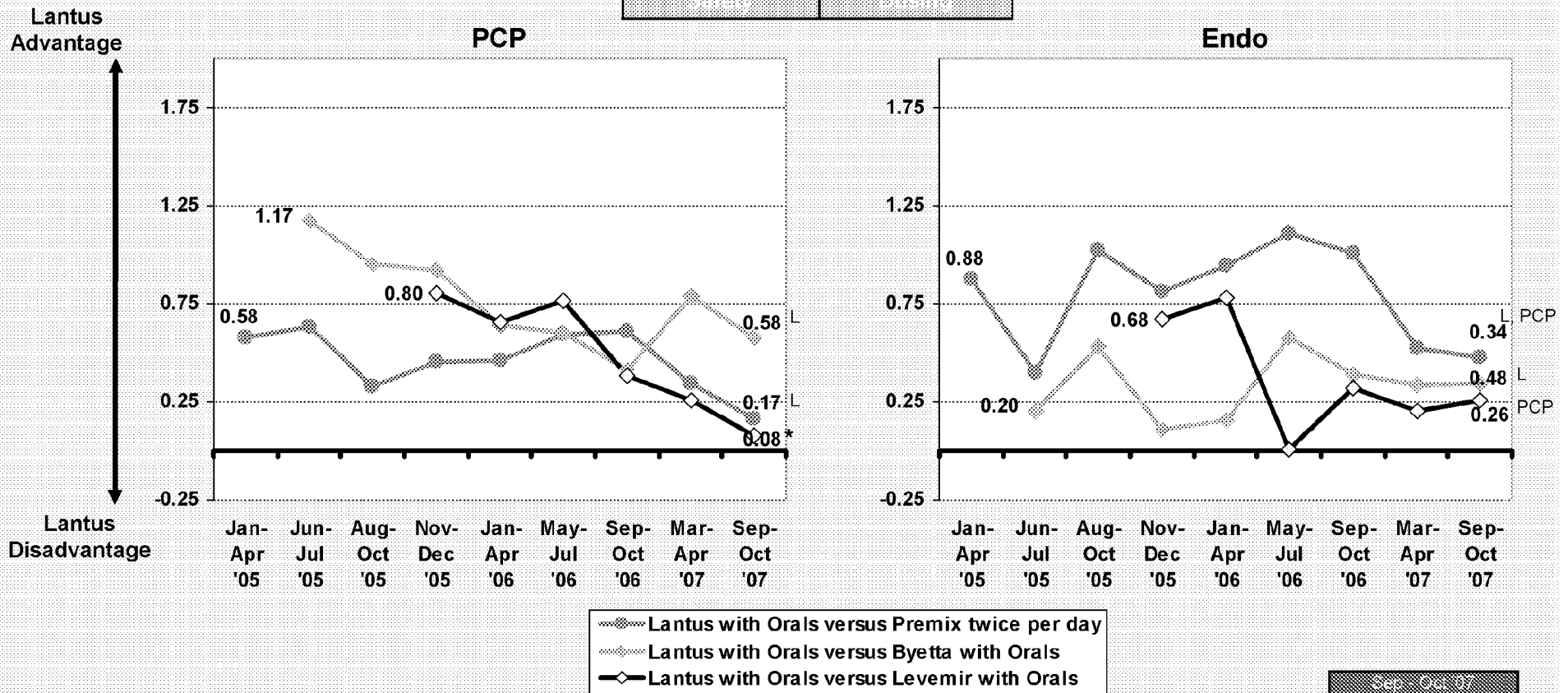
	Sep 0 to Sep 17	
	PCP	Endo
LAN	125	76
LEV	105	74



Both PCPs and Endos rate Lantus at an advantage over Levemir for 24-hour glucose control; Premix and Byetta have improved in this attribute over the past year

**Lantus vs. Competitors Performance Ratings – Selected Attributes:
Glucose control, as defined by HbA1c levels <7 – by Specialty**

Efficacy	Weight
Safety	Balance



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B. On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

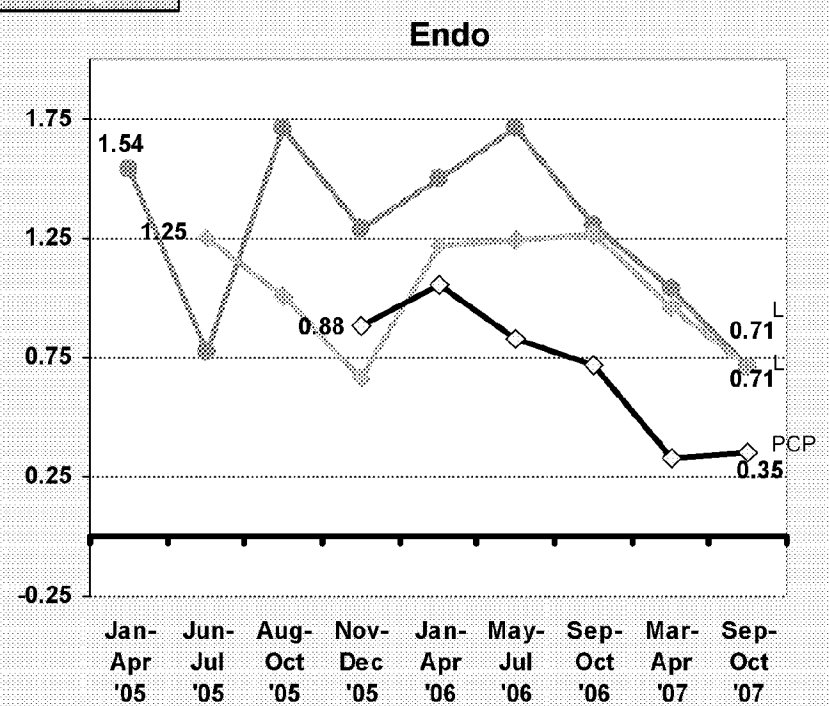
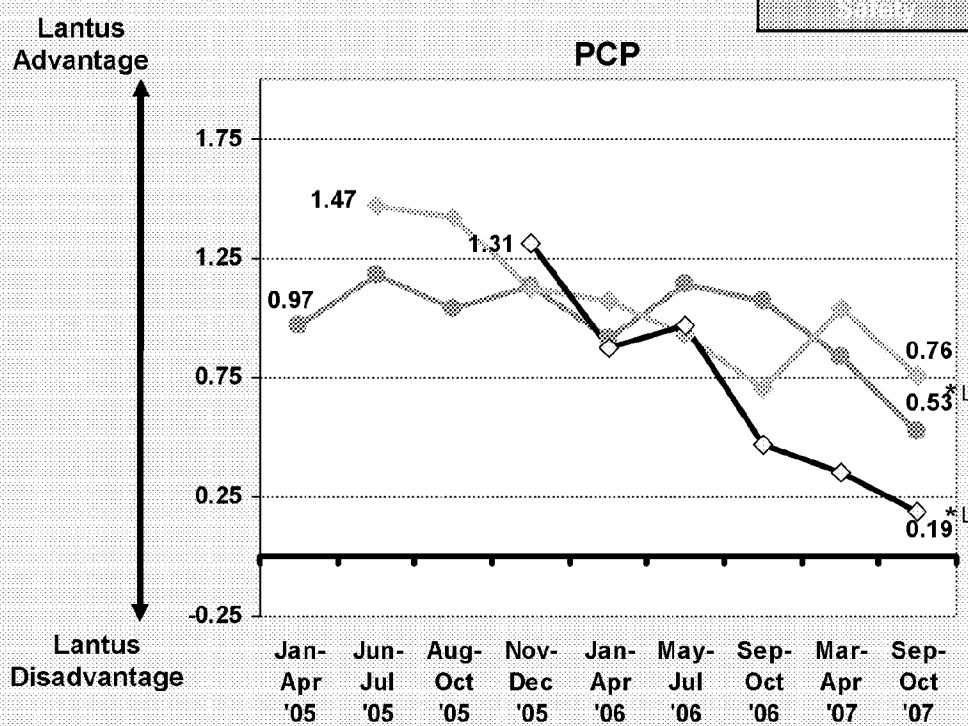
	Jan-Apr '05	Jan-Apr '06
LAN	125	76
LEV	105	74
BYT	115	75



Both PCPs and Endos rate Lantus at an advantage over Levemir for 24-hour glucose control; Premix and Byetta have improved in this attribute over the past year

**Lantus vs. Competitors Performance Ratings – Selected Attributes:
Provides 24-hour glucose control – by Specialty**

Efficacy	Weight
Safety	Balance



- ◆ Lantus with Orals versus Premix twice per day
- Lantus with Orals versus Byetta with Orals
- Lantus with Orals versus Levemir with Orals



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B. On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

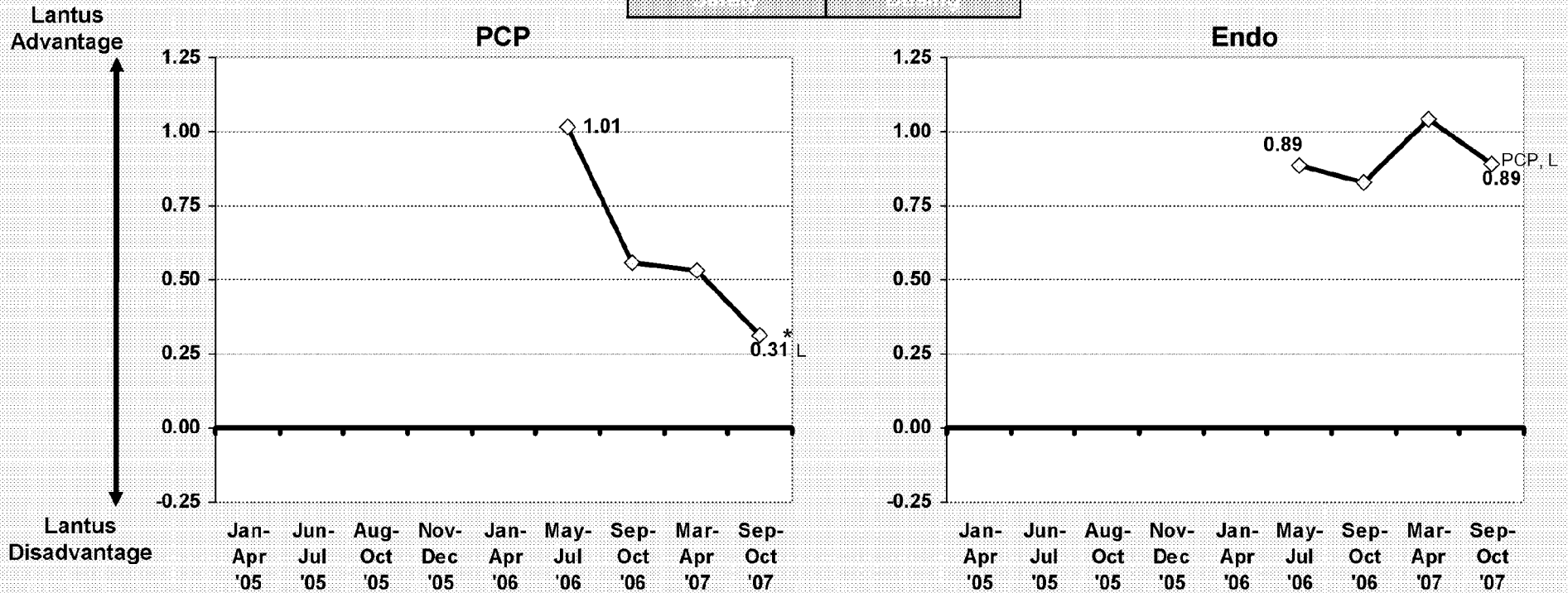
	Jan-Apr '07	May-Jul '07
LAN	125	76
LEV	105	74
BYT	115	75



Lantus' advantage over Levemir on Provides 24-hour control with one daily injection remains high with Endos while Levemir continues to close the gap with PCPs

Lantus vs. Competitors Performance Ratings – Selected Attributes:
Provides 24-hour control with one daily injection – by Specialty

Efficacy	Weight
Safety	Balance



- ◆ Lantus with Orals versus Premix twice per day
- ◆ Lantus with Orals versus Byetta with Orals
- ◆ Lantus with Orals versus Levemir with Orals



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B: On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

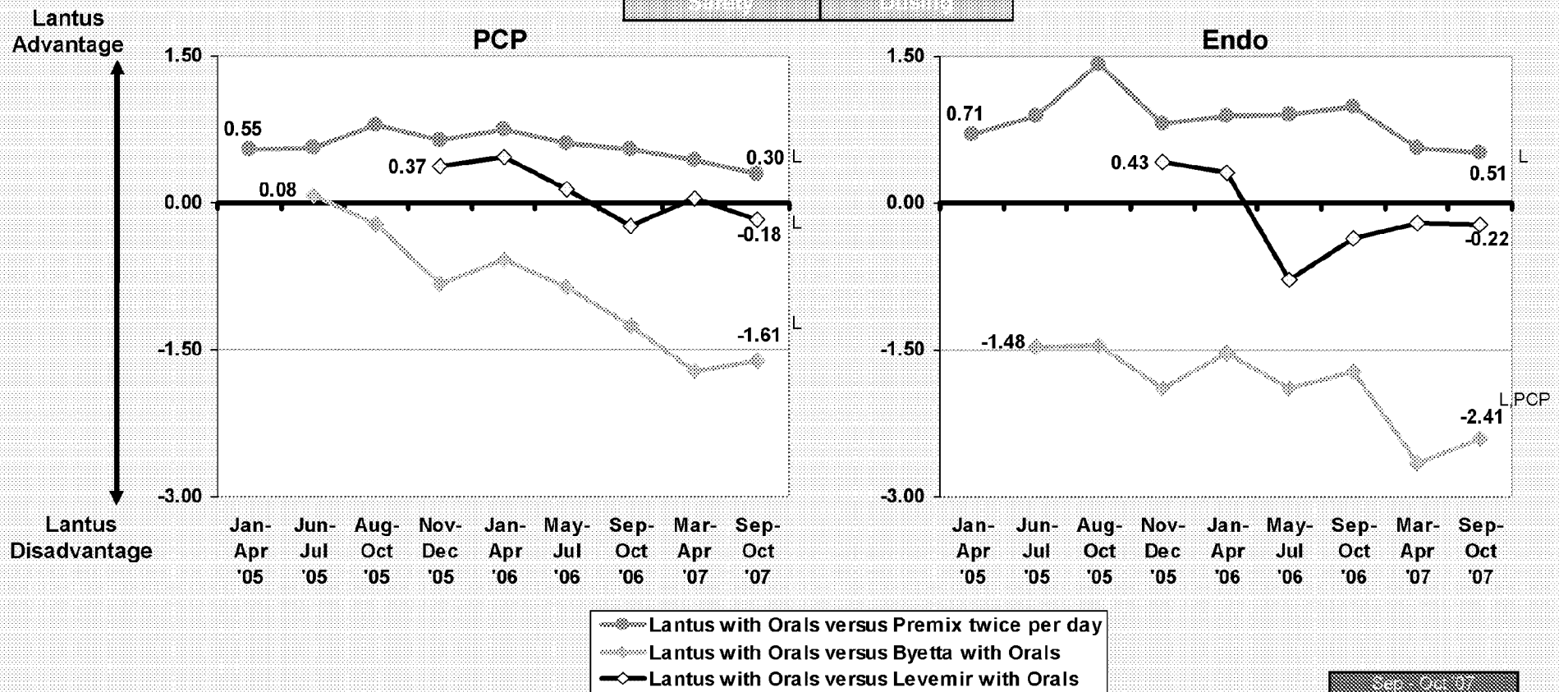
	PCP	Endo
LAN	125	76
LEV	105	74
BYT	115	75



PCPs and Endos rate Levemir and Byetta at an advantage over Lantus for Low degree of weight gain, while Lantus is perceived as superior to Premix

Lantus vs. Competitors Performance Ratings – Selected Attributes:
Low degree of weight gain – by Specialty

Efficiency	Weight
Safety	Busina



Source: COMPASS Physician ATU Tracking Study
 Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B: On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

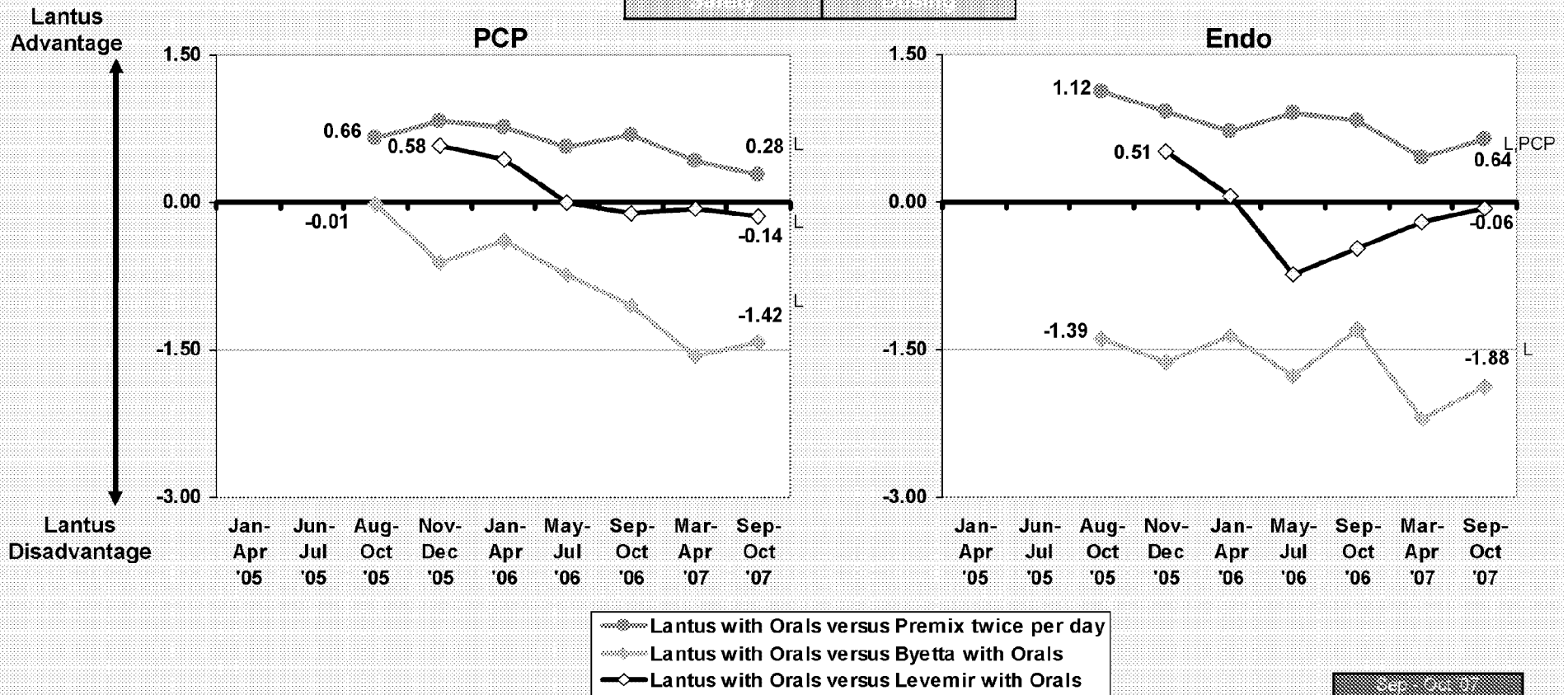
	Sep-06	Oct-07
LAN	125	76
LEV	105	74
BYT	115	75



Over the past year, Lantus has steadily closed the gap against Levemir on Weight-neutral effect among Endos

Lantus vs. Competitors Performance Ratings – Selected Attributes:
Weight-neutral effect – by Specialty

Efficiency	Weight
Safety	Boiling



Source: COMPASS Physician ATU Tracking Study
Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B: On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

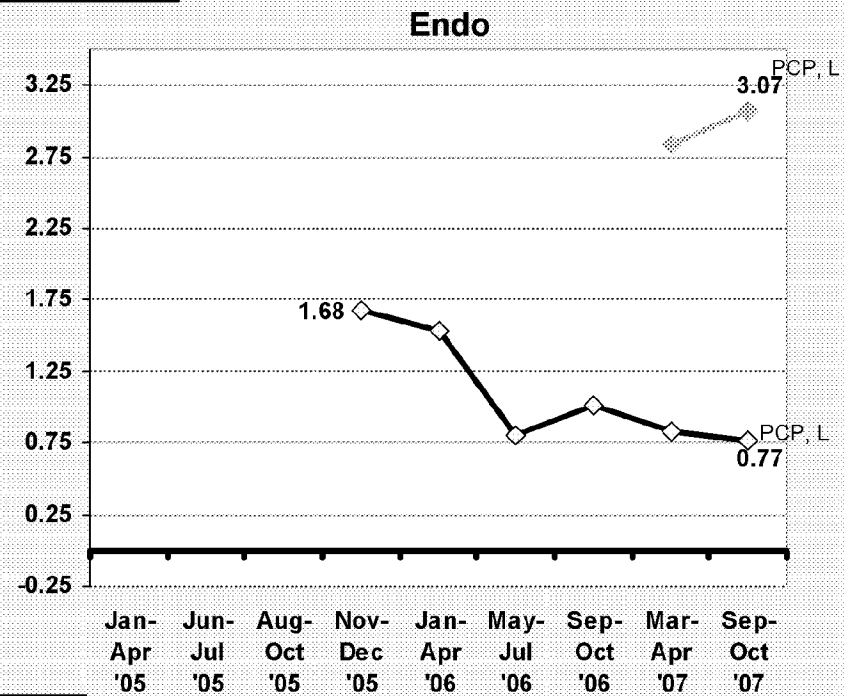
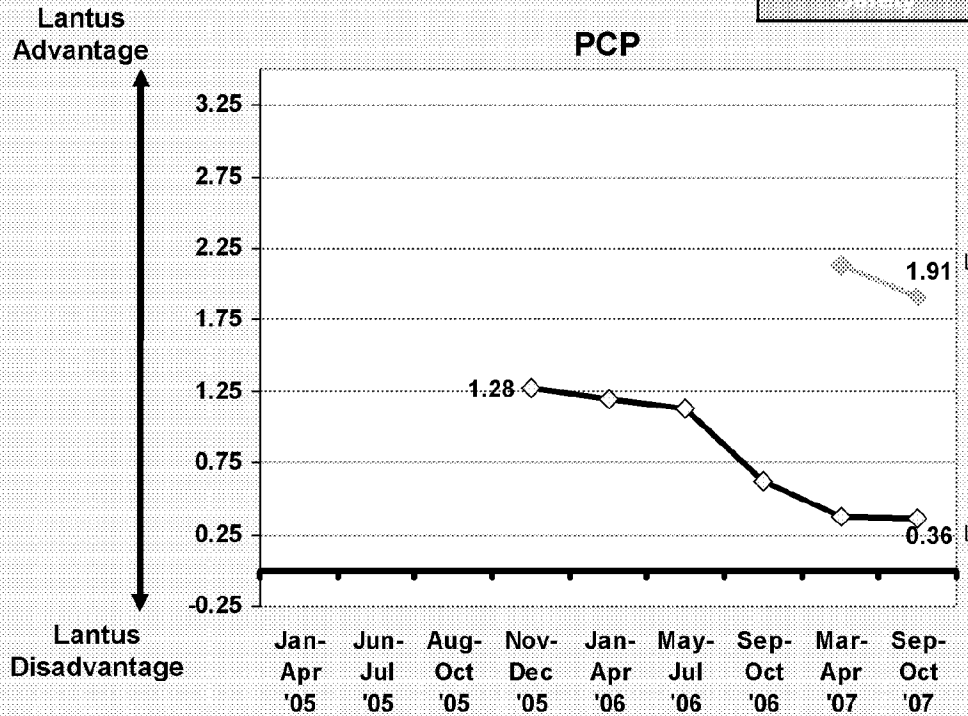
	Sep-06	Oct-07
LAN	125	76
LEV	105	74
BYT	115	75



Despite steady gains by Levemir, the Lantus advantage in *Once daily dosing* is still significant; Endos perceive a greater advantage than do PCPs

Lantus vs. Competitors Performance Ratings – Selected Attributes:
Provides once-daily dosing – by Specialty

Byetta	Levemir
Specialty	Dosing



◆ Byetta
◆ Levemir



Source: COMPASS Physician ATU Tracking Study
Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B. On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

	PCP	Endo
LAN	125	76
LEV	105	74
BYT	115	75

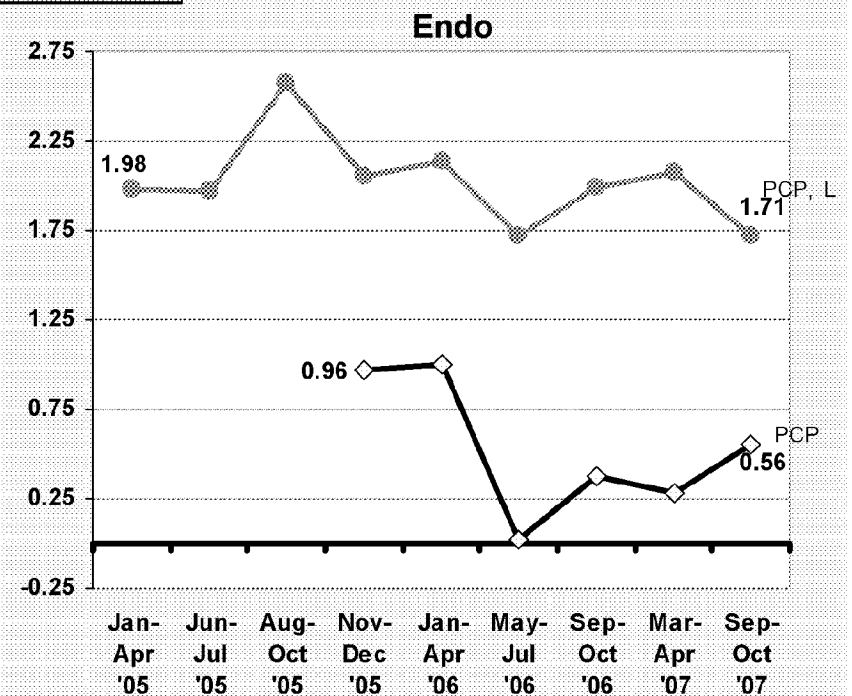
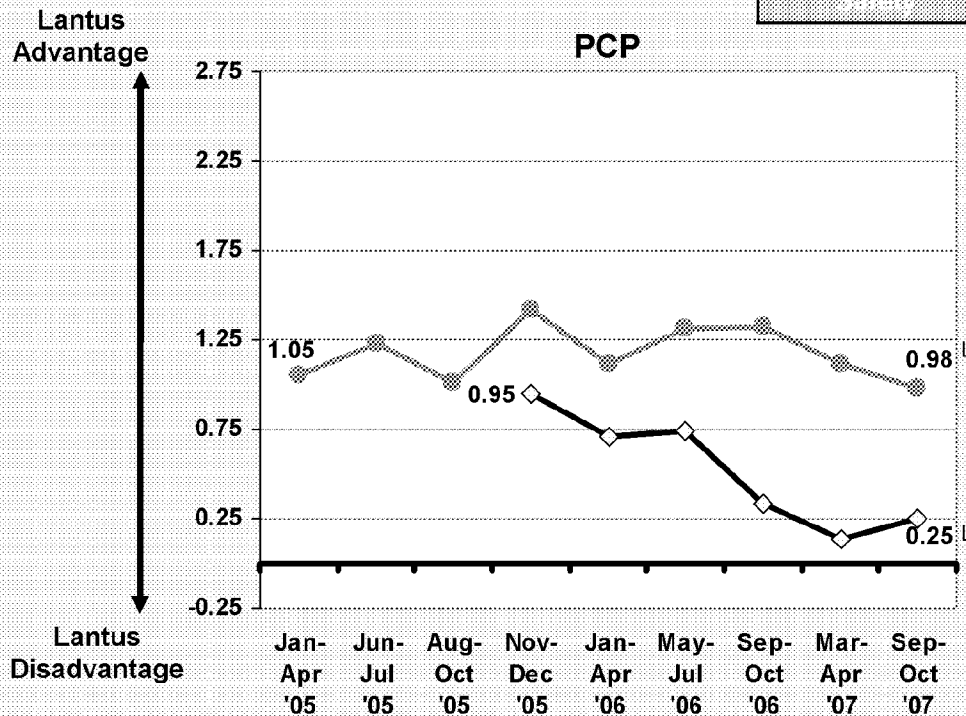
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The gap between Lantus and Levemir on *Mimics normal basal insulin release* has shown an upward trend amongst PCPs over the last eighteen months

Lantus vs. Competitors Performance Ratings – Selected Attributes:
Mimics normal basal insulin release – by Specialty

Byetta	Levemir
Safety	Dosing



- ◆ Lantus with Orals versus Premix twice per day
- ◆ Lantus with Orals versus Byetta with Orals
- ◆ Lantus with Orals versus Levemir with Orals



Source: COMPASS Physician ATU Tracking Study
Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B: On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

	Jan-Apr '07	May-Jul '07
LAN	125	76
LEV	105	74
BYT	115	75

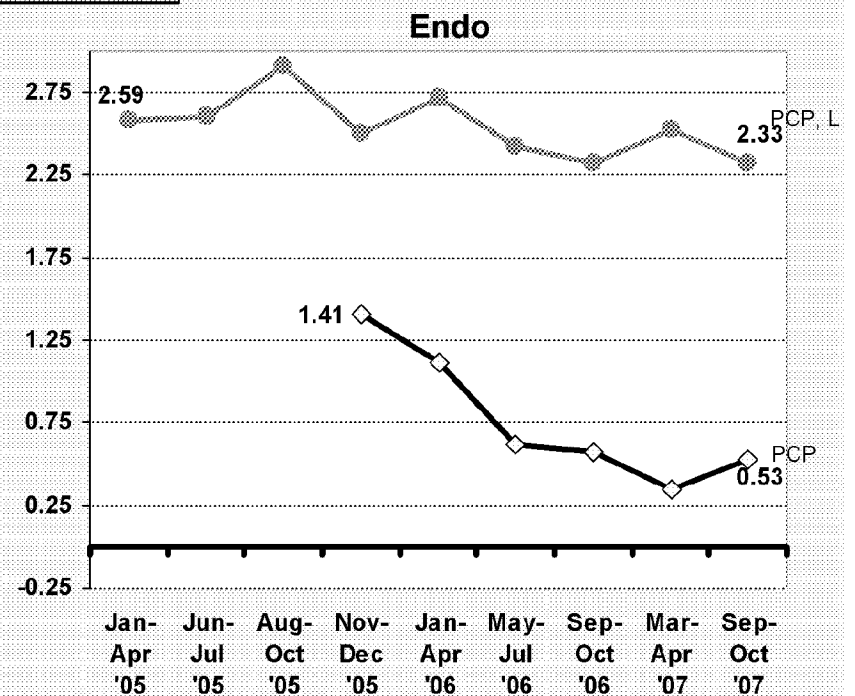
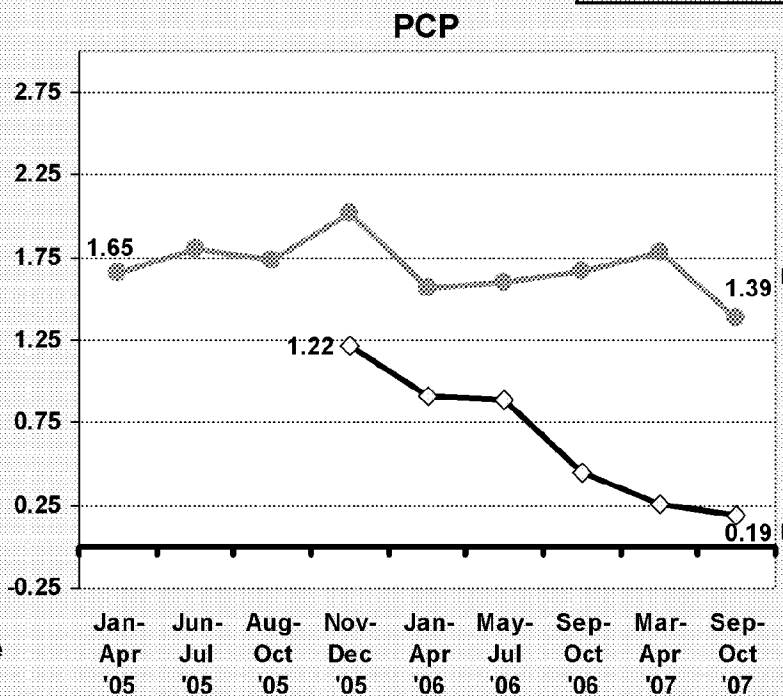


Endos report significantly higher scores for Lantus relative to Levemir on *Has no unwanted peak*

Lantus vs. Competitors Performance Ratings – Selected Attributes:
Has no unwanted peak – by Specialty

Endo	PCP
Safety	Dosing

Lantus Advantage ↑
↓ Lantus Disadvantage



- ◆ Lantus with Orals versus Premix twice per day
- ◆ Lantus with Orals versus Byetta with Orals
- ◆ Lantus with Orals versus Levemir with Orals



Source: COMPASS Physician ATU Tracking Study
Note: Data are weighted by physician population. L = statistically different between Lantus and [Product]. Stat testing performed with paired data points, using data only from physicians who answered for both regimens. PR3B. On a scale of 1 to 7, where 1 means "Far inferior to all other products" and 7 means "Far superior to all other products," please rate how well you feel each product performs on these attributes/functions for Type 2 Patients.

	Jan-Apr '05	Jan-Apr '06
LAN	125	76
LEV	105	74
BYT	115	75



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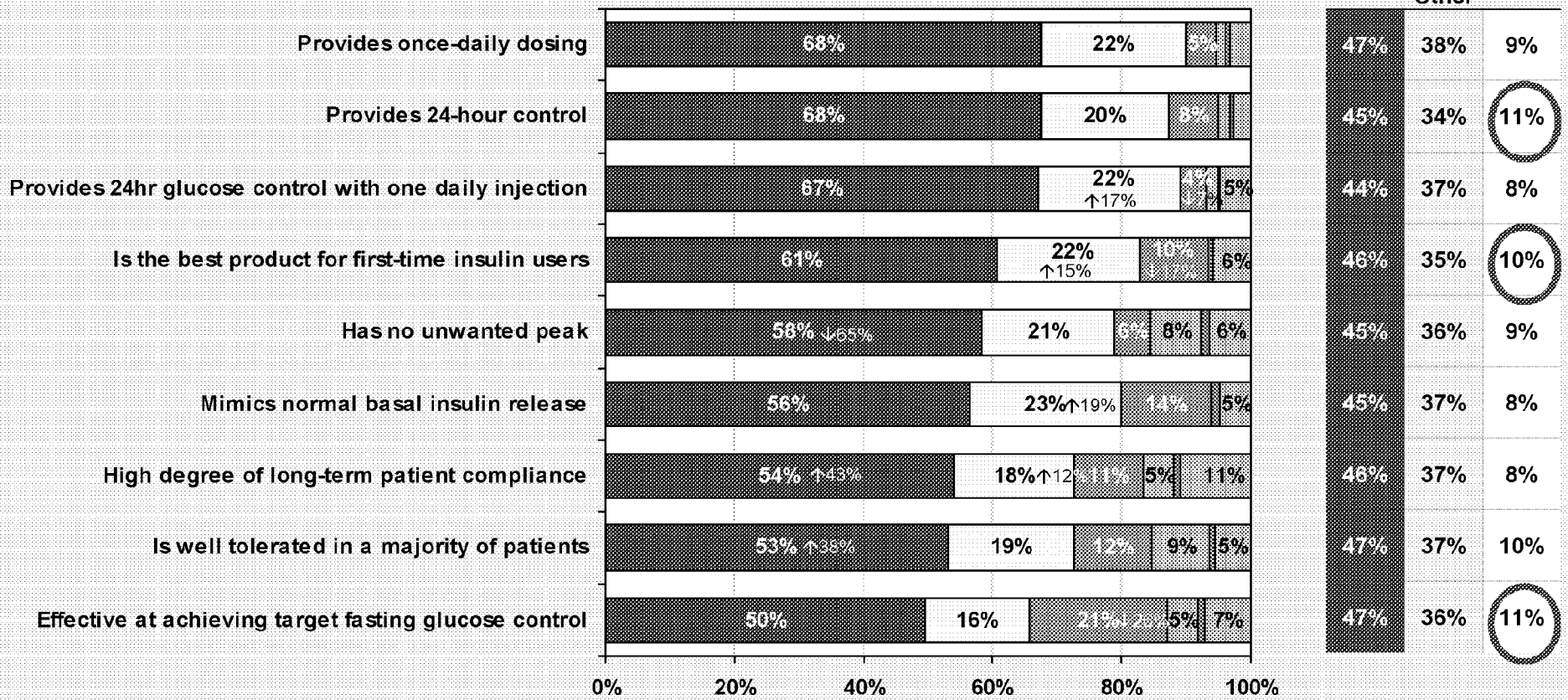


In Sep-Oct '07, Lantus maintained its ownership of *Provides once-daily dosing* while Levemir captured increasing share of other important attributes including *Provides 24 hour control with one daily injection*

Message Association: by Total

Association with Lantus

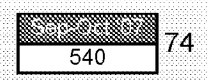
Product Associated: Lantus Any Other Diff.



Legend: ■ Lantus □ Levemir ▨ Pre-mix ▩ Byetta ▤ Long / Intermediate Acting ▥ Other / Don't Know



Source: COMPASS Sales Force Tracking Study, IMS Lantus NRx Data Jun-Aug '07
 Note: Data are weighted by reach. ME7: For each of the following statements please select the one diabetes product that you believe is best associated with the statement.



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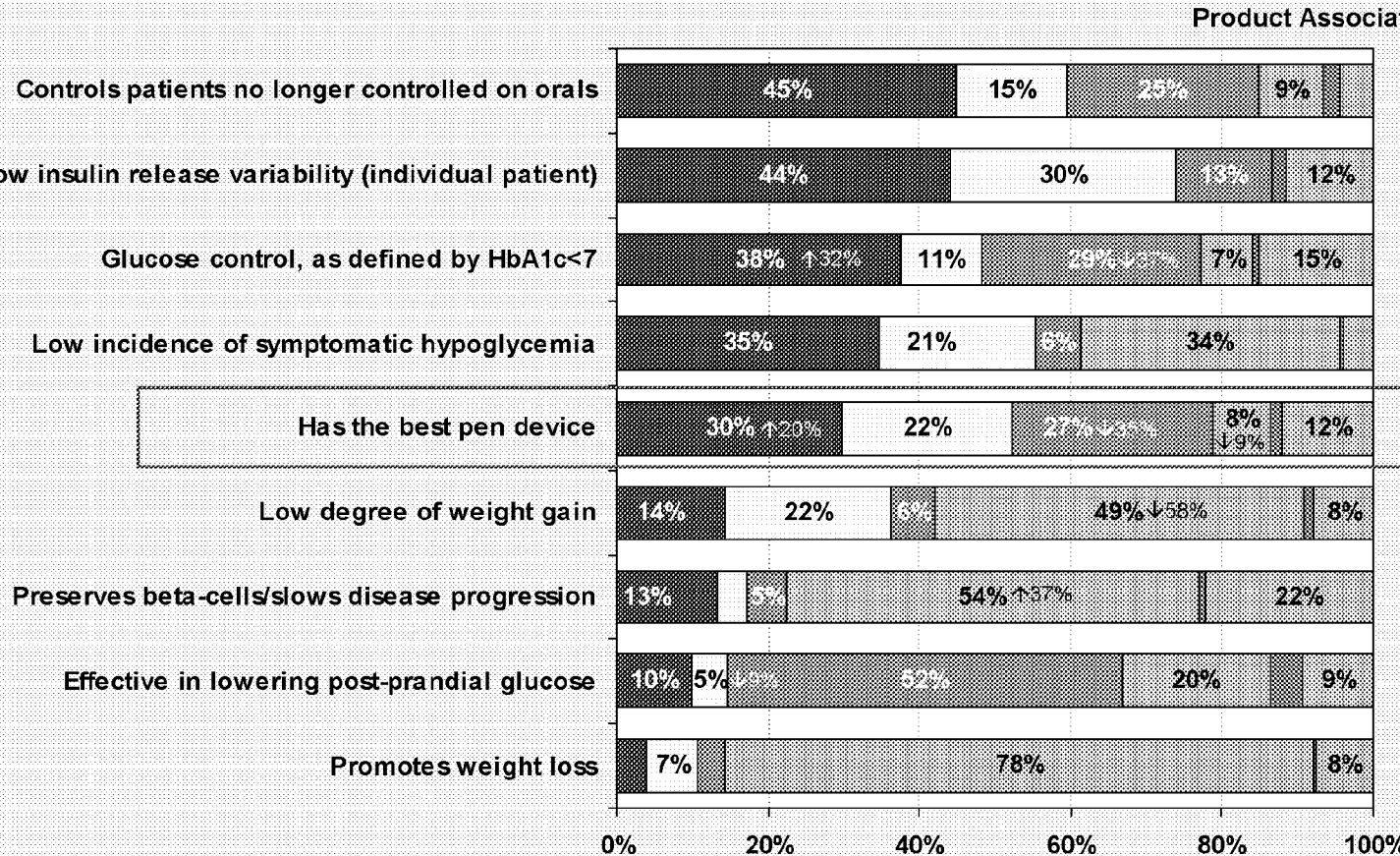
PTX-0739.0074
 Sanofi Exhibit 2146.074
 Mylan v. Sanofi
 IPR2018-01675



Physicians associate Lantus with the message *Has the best pen device* more than any other product

Message Association: by Total

Association with Lantus



Lantus NRx Share

Product Associated:	Lantus	All Other	Diff.
Controls patients no longer controlled on orals	47%	38%	9%
Low insulin release variability (individual patient)	45%	41%	5%
Glucose control, as defined by HbA1c<7	47%	39%	8%
Low incidence of symptomatic hypoglycemia	46%	41%	5%
Has the best pen device	45%	41%	4%
Low degree of weight gain	46%	42%	5%
Preserves beta-cells/slows disease progression	45%	42%	3%
Effective in lowering post-prandial glucose	41%	42%	-2%
Promotes weight loss	41%	42%	-1%

Lantus
 Levemir
 Pre-mix
 Byetta
 Long / Intermediate Acting
 Other / Don't Know



Source: COMPASS Sales Force Tracking Study, IMS Lantus NRx Data Jun-Aug 07
 Note: Data are weighted by reach. ME7: For each of the following statements please select the one diabetes product that you believe is best associated with the statement.

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 Mylan v. Sanofi
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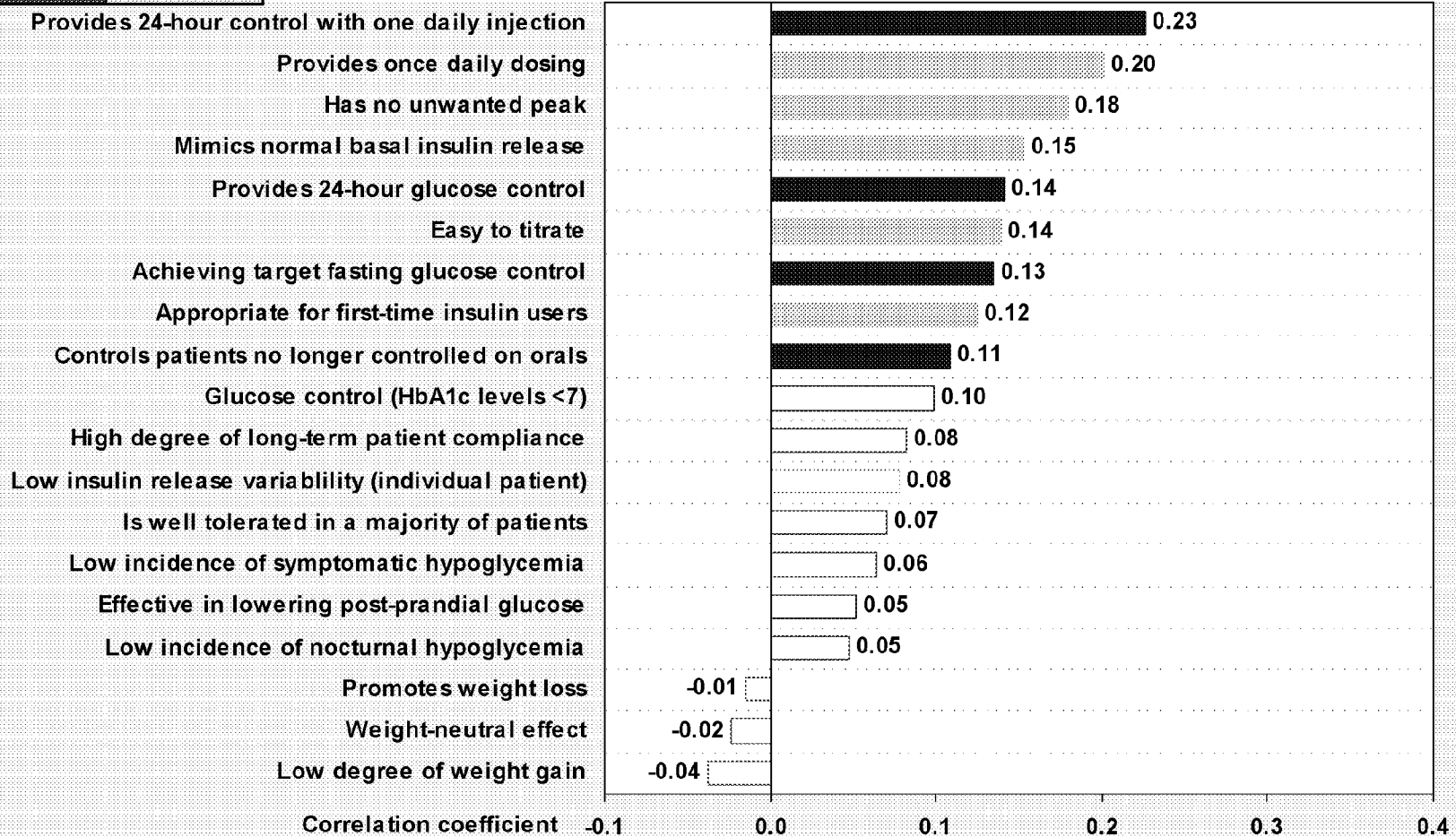
- ◆ Introduction
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- ◆ Product Perceptions
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 - Treatment Pathway
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When choosing between Lantus and Levemir, *once daily dosing and 24-hour control with one injection* are the most important attributes (derived)

Efficacy	Weight
Safety	Dosing

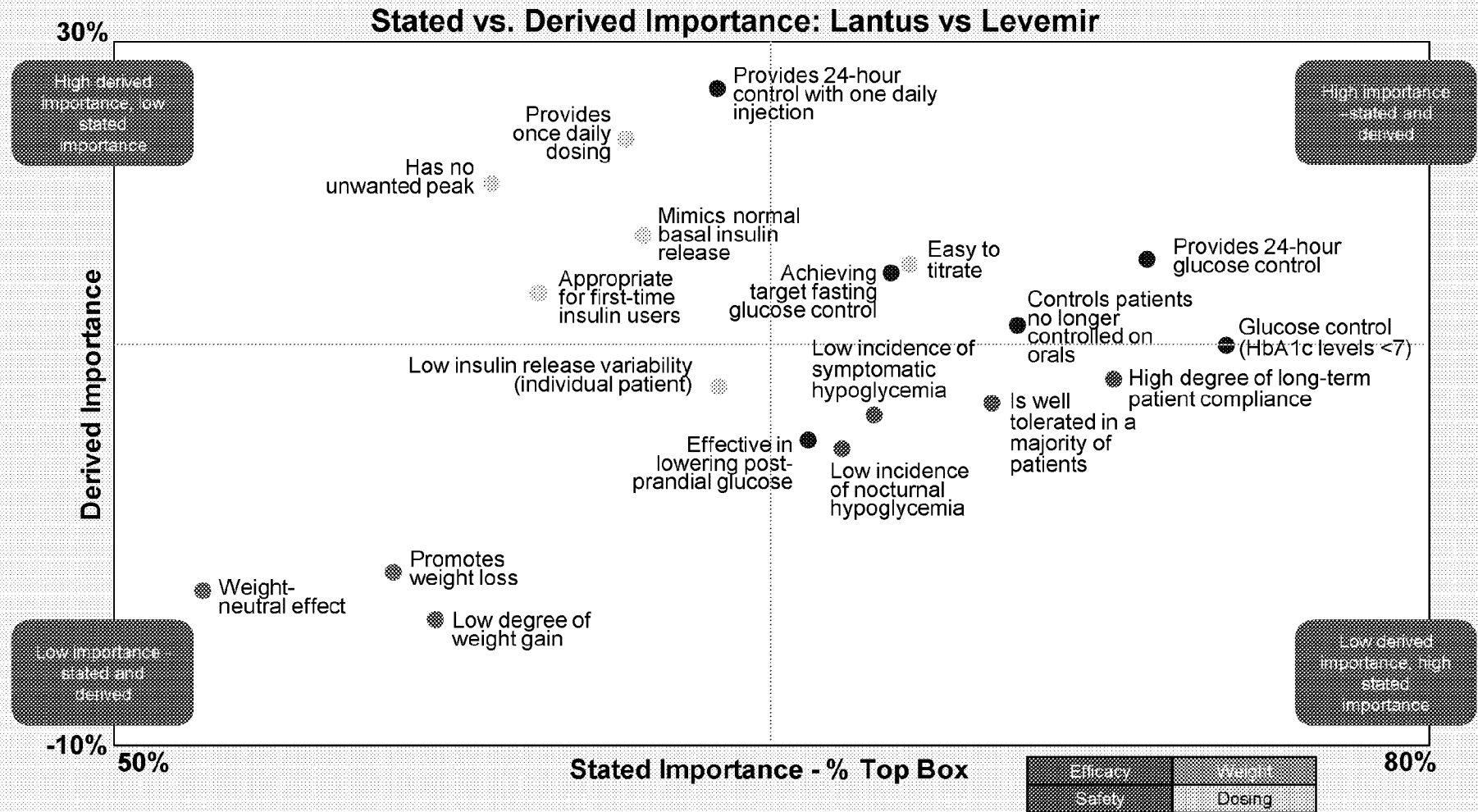
Attribute to NRx Share Correlations: Lantus vs. Levemir



Source: Lantus COMPASS Physician ATU Tracking Study, IMS Lantus NRx Data Jun-Aug '07
 PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients.
 Please consider all other therapies that you currently use with your Type 2 diabetes patients. Statistically different at 95% between products as indicated by filled gaps. Derived importance correlation run for Lantus and Levemir only.



Several of the attributes most highly correlated with NRx share are dosing attributes, in which Lantus hold significant performance advantages



Source: COMPAS Physician ATU Tracking Study, IMS Select Insulin NRx Data Jun-Aug '07
 PR3A: For each of the factors listed below, please indicate how important each factor is in your selection of a particular diabetes product for Type 2 patients. PR3B: On a scale of 1 to 7, please rate how well you feel each therapy performs on these attributes/functions for Type 2 patients. Derived importance correlation run for Lantus and Levemir only.





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 - Insulin Focus
 - Byetta and Januvia Focus
- ◆ Sales Force
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The objective of the treatment pathway section is to understand physician strategies for treating diabetes and how they are changing given multiple new product entries

Key Questions

Treatment Regimens

- ◆ What are the most common treatment pathways physicians use to treat diabetes?
- ◆ How and when are physicians utilizing newer product classes?

Length of Therapy

- ◆ What is the length of time for each line of therapy?

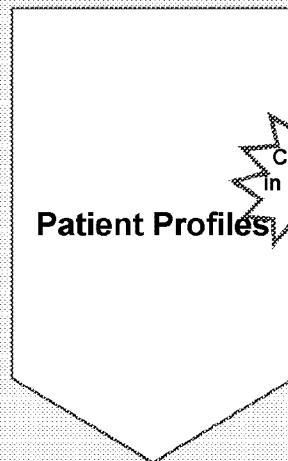
Insulinization / Referral

- ◆ How long does a physician wait to initiate insulin or refer the patient to a specialist?
- ◆ How is the time to insulin affected by previous product choices?

Sub Group Analyses

- ◆ How do the results of above questions vary by PCP Vs. Endo and by Patient Type

Approach



- Physicians were randomly assigned **one** of two patient profiles (shown below)



Patient Profiles:

Patient 1 - Healthier

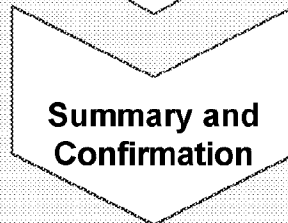
- 45 years old
- BMI of 29 (overweight, but not obese)
- HbA1c of 7.5
- Fasting glucose of 155

Patient 2 – Less Healthy

- 45 years old
- BMI of 34 (obese)
- HbA1c of 9.5
- Fasting glucose of 200
- Treated for dyslipidemia & hypertension



- Physicians specified treatment choices for each line of therapy until the line following the addition of insulin or until referral to another physician
- Following completion of a line of therapy, physicians estimated length of time patients' HbA1c level would be controlled before the treatment needed adjustment



- Physicians asked to confirm overall time from first treatment to initiation of *insulin* or *referral to another physician*

*Patient 1 BMI increased from 27 to 29 and HbA1c level increased from 7.0 to 7.5 in Sep-Oct '07



Each physician answers the treatment pathway questions with the one particular patient in mind

Treatment Pathway Example – ILLUSTRATION ONLY

[View patient characteristics](#)

Please confirm that we have accurately captured your treatment pathway and timing of treatments for this particular patient.

First line: Biguanide metformin and Sulfonylureas for 3 year(s) and 6 month(s)
Second line: Biguanide metformin and TZDs for 3 year(s) and 0 month(s)
Third line: Fixed dose combinations and Byetta for 1 year(s) and 6 month(s)
Fourth line: Byetta and Insulin for 10 year(s) and 0 month(s)
Fifth line: Byetta and Insulin for 10 year(s) and 0 month(s)

The overall time from first treatment to initiation of insulin: 8 year(s) and 0 month(s)

Is this correct?

Yes
 No

[Next](#)

0%

Need Help? [Click Survey](#) or call toll-free 1-888-799-5

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After insulin is FIRST initiated, physicians are asked one additional line of therapy

selected, physicians specify the appropriate insulin(s) and the number of doses per day

selected, physicians specify the appropriate combination(s)

responses visible as is advance er lines



Each physician answers the treatment pathway questions with the one particular patient in mind

Treatment Pathway Example – ILLUSTRATION ONLY

View patient characteristics

Please confirm that we have accurately captured your treatment pathway and timing of treatments for this particular patient.

First line: Biguanide metformin and Sulfonylureas for 3 year(s) and 6 month(s)

Second line: Biguanide metformin and TZDs for 3 year(s) and 0 month(s)

Third line: Fixed dose combinations and Byetta for 1 year(s) and 6 month(s)

Fourth line: Byetta and Insulin for 10 year(s) and 0 month(s)

Fifth line: Byetta and Insulin for 10 year(s) and 0 month(s)

The overall time from first treatment to initiation of insulin: 8 year(s) and 0 month(s).

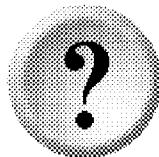
Is this correct?

- Yes
- No

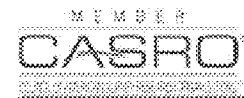
By choosing "No",
physicians can return
to a previous line of
therapy for revising

Next

0% 100%



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or call toll-free 1-888-799-5311



COMPASS



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- ◆ Introduction
- ◆ Key Findings
- ◆ Awareness and Trial
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Endos have more aggressive HbA1c thresholds than PCPs for both patient types; however, the number of products used and reported time to insulin do not differ by specialty

Data on this slide are still being verified/validated – meanwhile, do not use



Source: COMPASS Sales Force Tracking Study

Note: TXP5: Length of time controlled on this therapy before switching to next therapy. TXP6: HbA1c level at which you alter the patient's therapy. * Average line of therapy and length of time until insulin include only physicians who initiate insulin in lines 1-6 (exclude those who refer patient prior to insulin). Patient 1 profile revised Sep-Oct '07.

	Sep	Oct	
P1	191	70	84
P2	189	85	

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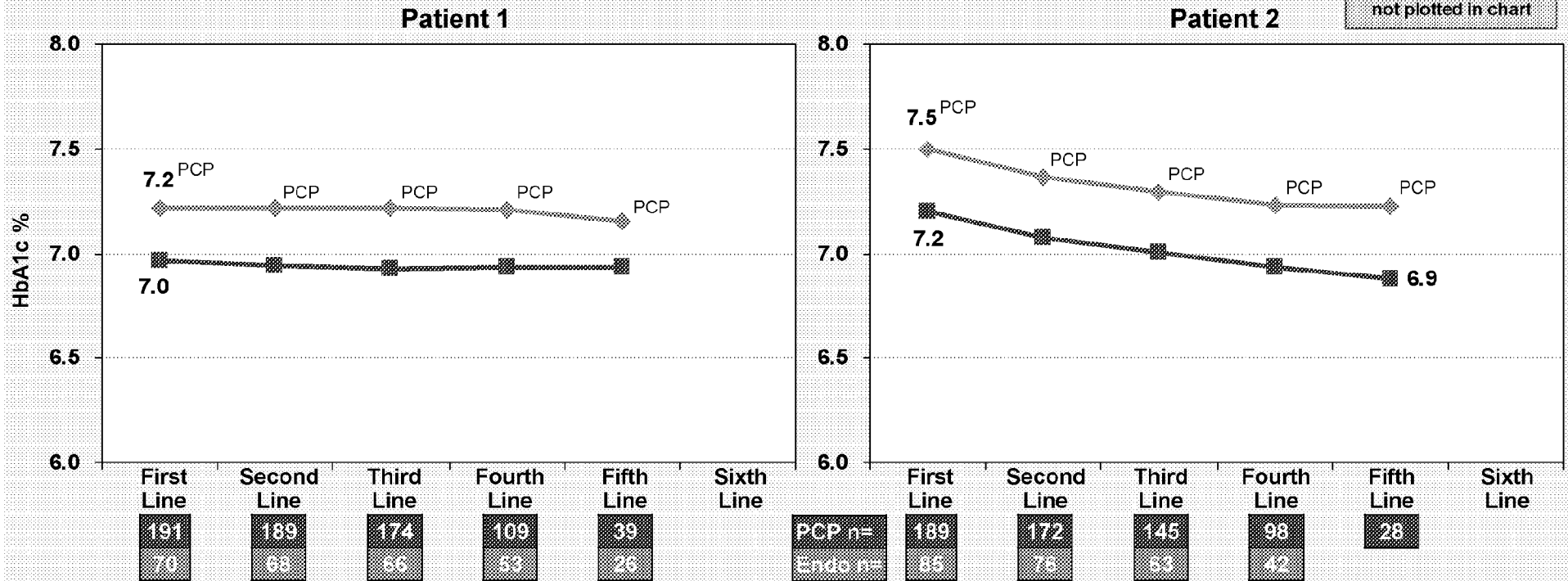
PTX-0739.0084
Sanofi Exhibit 2146.084
Mylan v. Sanofi
IPR2018-01675



Endos are more aggressive treaters with respect to HbA1c, regardless of patient type or line of therapy

HbA1c Level at which Therapy Changes: by Patient and Specialty

Note: n-sizes < 20 not plotted in chart



Patient 1 - Healthier

- 45 years old
- BMI of 29 (overweight, but not obese)
- HbA1c of 7.5
- Fasting glucose of 155

Patient 2 - Less Healthy

- 45 years old
- BMI of 34 (obese)
- HbA1c of 9.5
- Fasting glucose of 200
- Treated for dyslipidemia & hypertension

■ PCP ◆ Endo



Source: COMPASS Sales Force Tracking Study
 Note: TXP6: HbA1c level at which you alter the patient's therapy.

	PCP	Endo
P1	191	70
P2	189	85

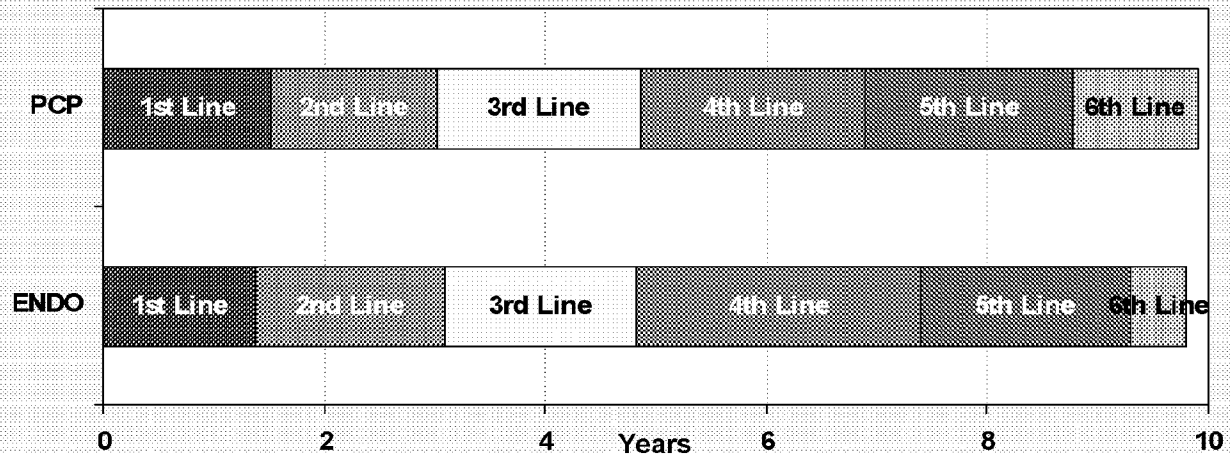


The length of each line of therapy does not differ significantly by specialty, but differences do exist by patient type; when Patient 1 is in the second line of therapy, Patient 2 has already moved to third line

Average Length of Line of Therapy: by Patient and Specialty

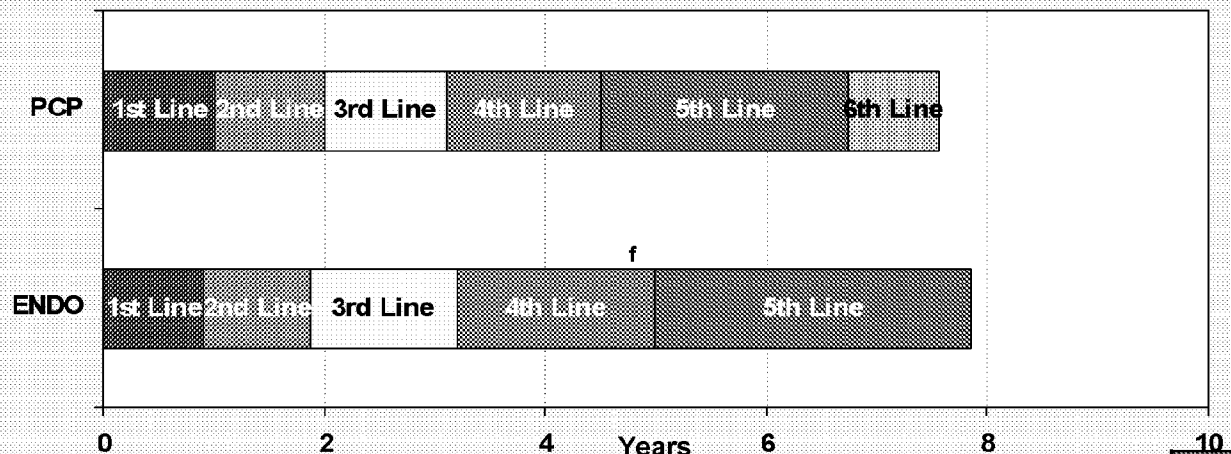
Patient 1 - Healthier

- 45 years old
- BMI of 29 (overweight but not obese)
- HbA1c of 7.5
- Fasting glucose of 155



Patient 2 - Less Healthy

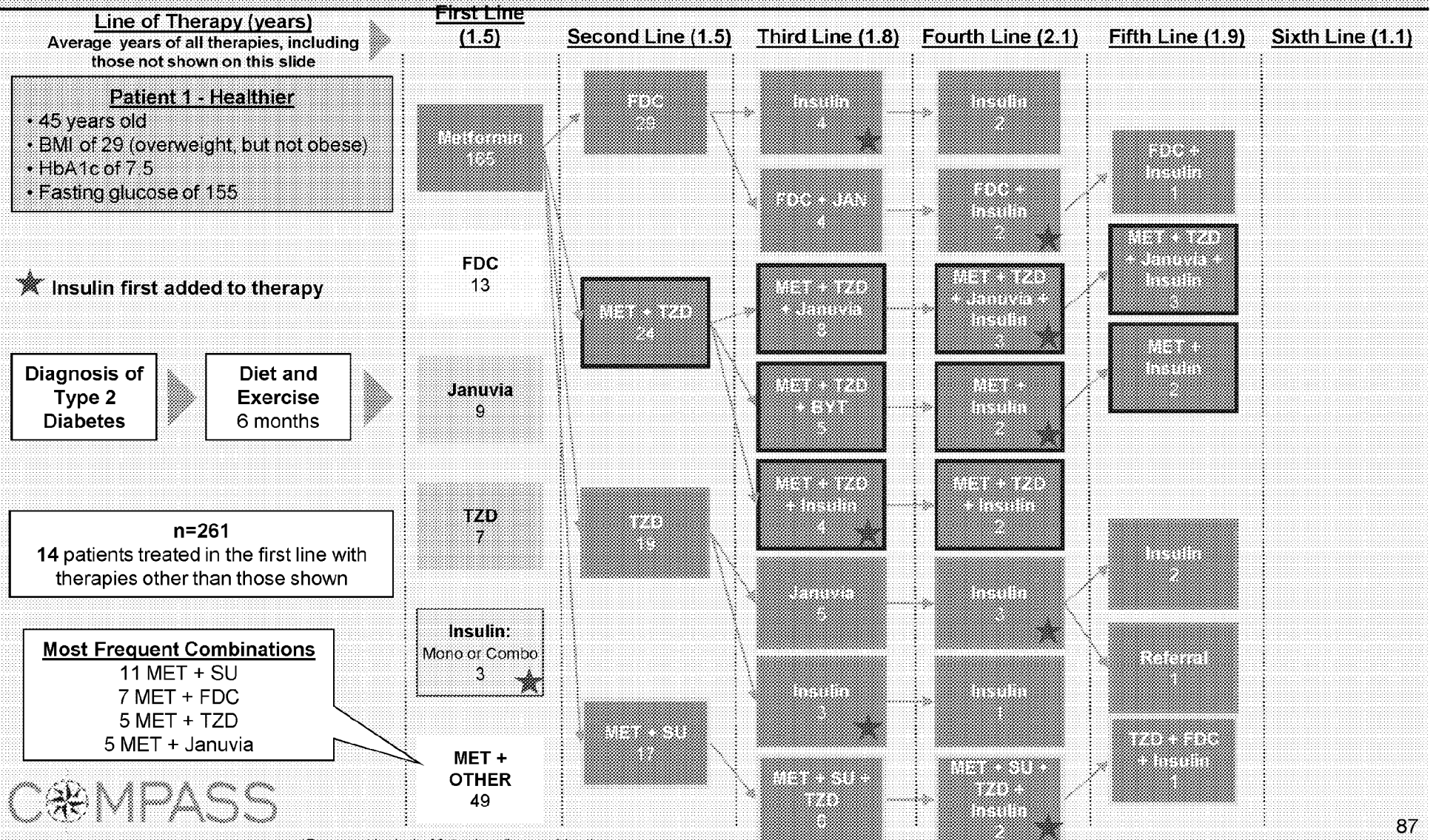
- 45 years old
- BMI of 34 (obese)
- HbA1c of 9.5
- Fasting glucose of 200
- Treated for dyslipidemia & hypertension



Source: COMPASS Sales Force Tracking Study
 Note: TXP5: Length of time controlled on this therapy before switching to next therapy. Patient 1 revised Sep-Oct '07.

	Sep '07	Oct '07	
P1	191	70	86
P2	189	85	

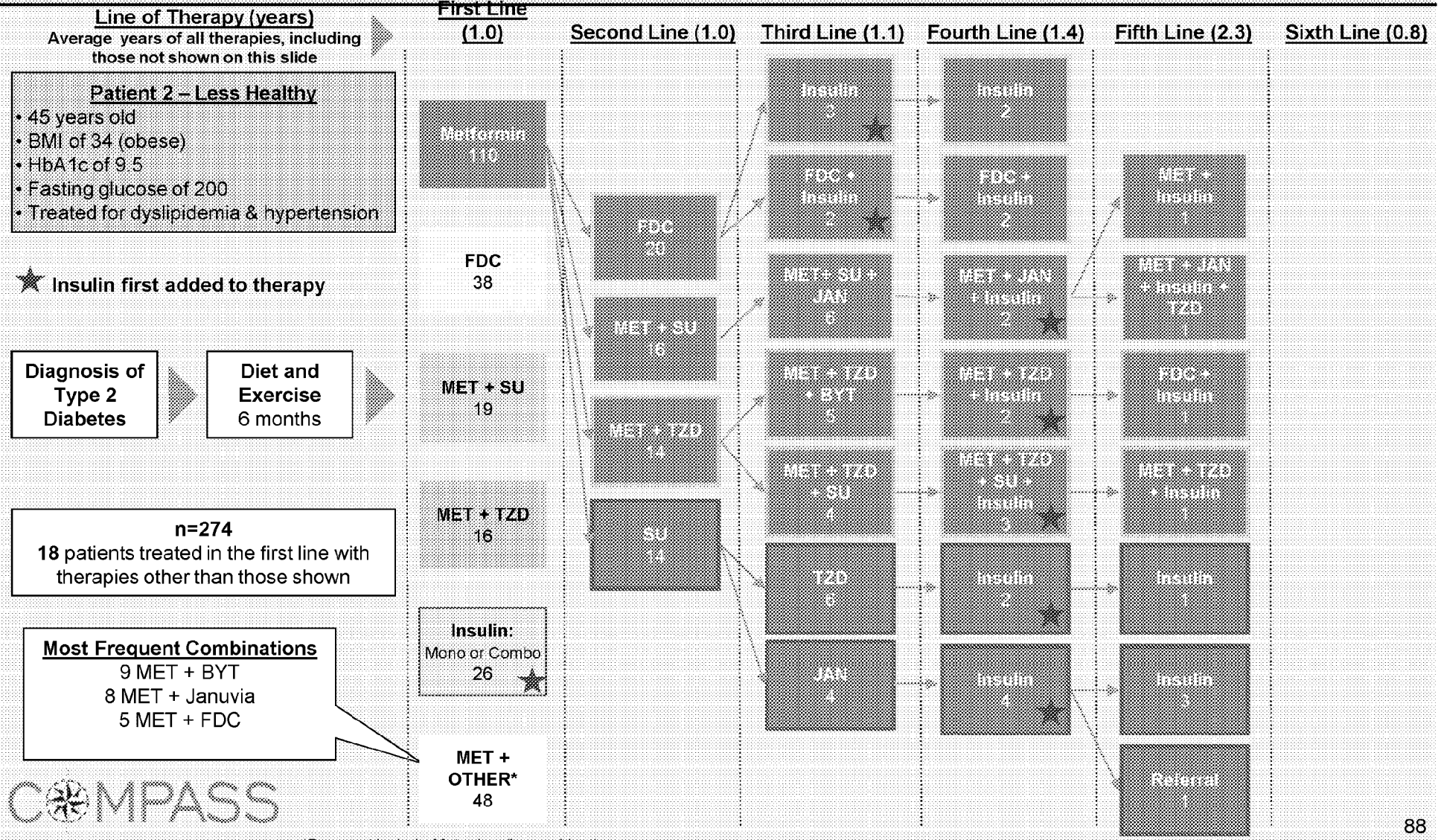
When treating healthier Patient 1, most physicians turn first to metformin and FDCs and tend to move to insulin by the third or fourth line of therapy



COMPASS



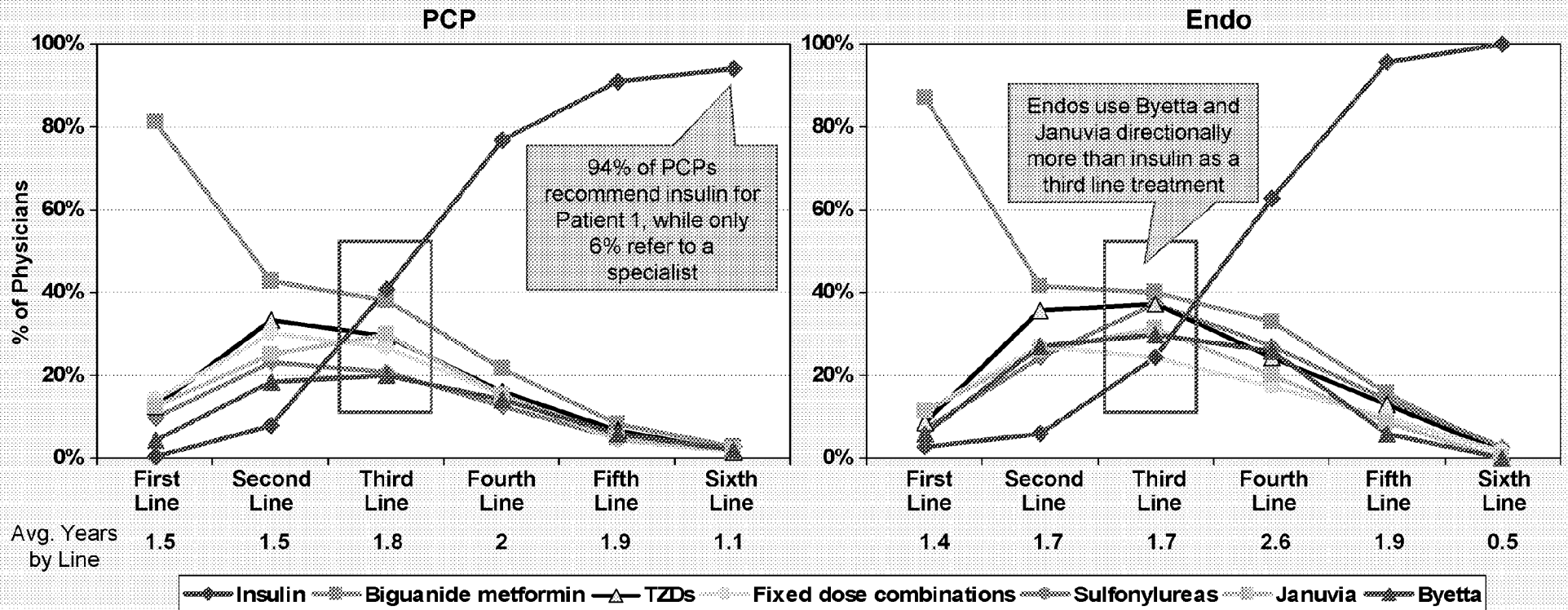
As with Patient 1, the majority of physicians begin Patient 2 on metformin monotherapy; however, FDCs are about three times more prevalent as a first line therapy for Patient 2





PCPs tend to recommend insulin earlier than Endos for Patient 1; Endos are more likely to add another oral, such as a TZD or SU before initiating insulin

Percentage of MDs Using Each Therapy Patient 1: by Specialty



94% of PCPs recommend insulin for Patient 1, while only 6% refer to a specialist

Endos use Byetta and Januvia directionally more than insulin as a third line treatment

Patient 1 - Healthier

- 45 years old
- BMI of 29 (overweight, but not obese)
- HbA1c of 7.5
- Fasting glucose of 155

Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? If you would recommend more than one medication for each any line of therapy for this patient, please check all that apply. If you would add treatments to a next line of therapy (rather than discontinuing a prior treatment) please select all treatments for that line of therapy, both prior and new treatments. Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. Question also asked for Meglitinides, Alpha-glucose inhibitors, and Referral, but data not shown for these options.

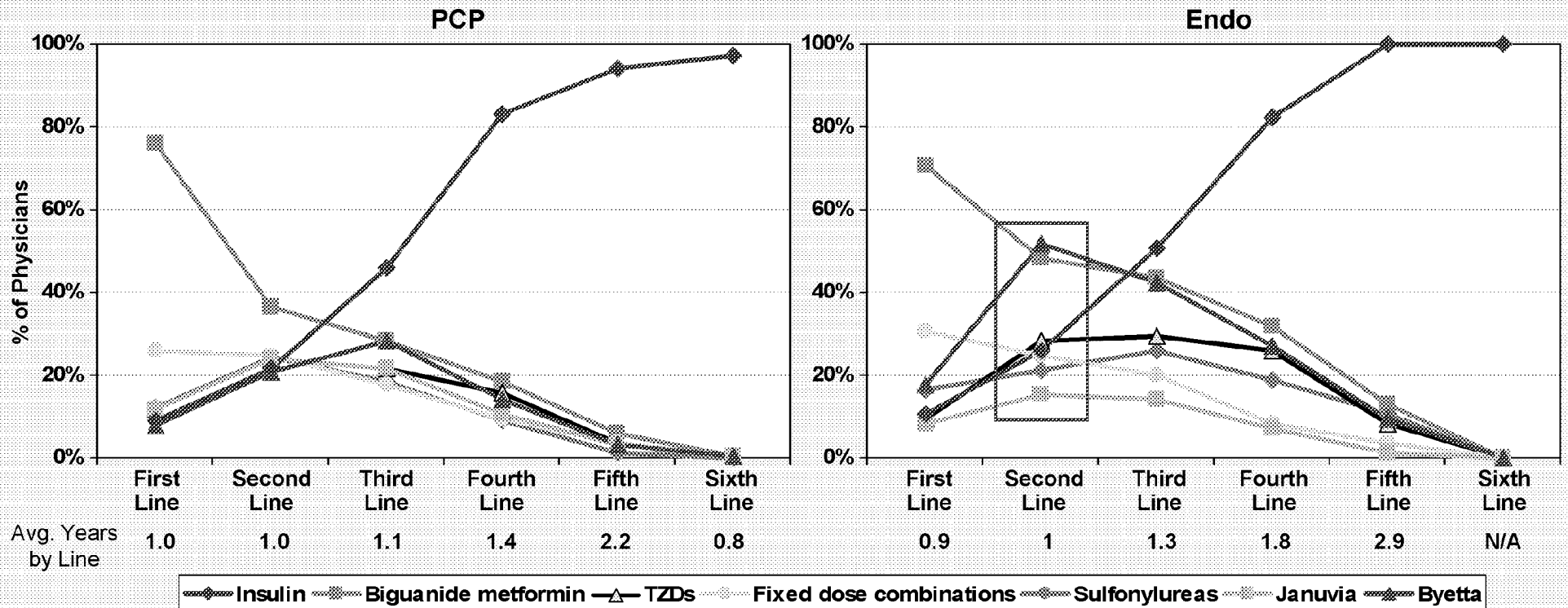
	PCP	Endo
P1	191	70
P2	189	85





Over 50% of Endos recommend Byetta as a second line treatment for Patient 2; Byetta use in the third line remains high, though slightly less than insulin

Percentage of MDs Using Each Therapy Patient 2: by Specialty



Patient 2 – Less Healthy

- 45 years old
- BMI of 34 (obese)
- HbA1c of 9.5
- Fasting glucose of 200
- Treated for dyslipidemia & hypertension

Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? If you would recommend more than one medication for each any line of therapy for this patient, please check all that apply. If you would add treatments to a next line of therapy (rather than discontinuing a prior treatment) please select all treatments for that line of therapy, both prior and new treatments. Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. Question also asked for Meglitinides, Alpha-glucose inhibitors, and Referral, but data not shown for these options.

	Insulin	Byetta	Total
P1	191	70	90
P2	189	85	





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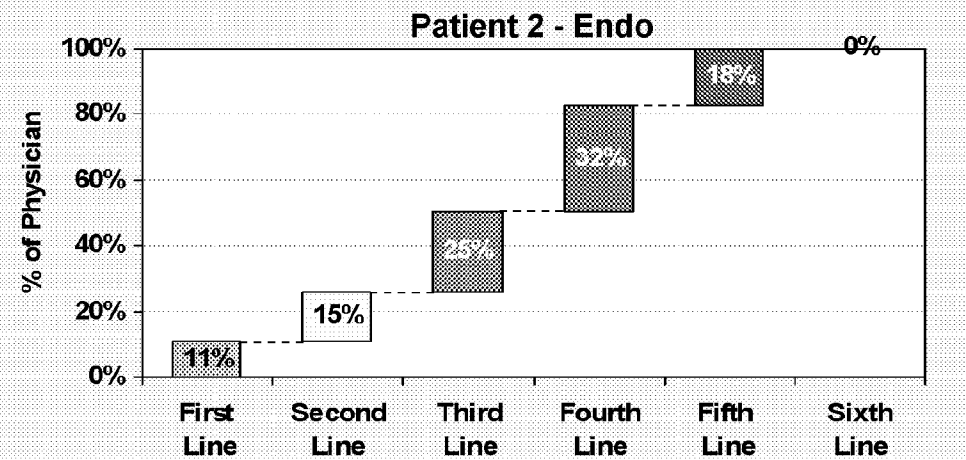
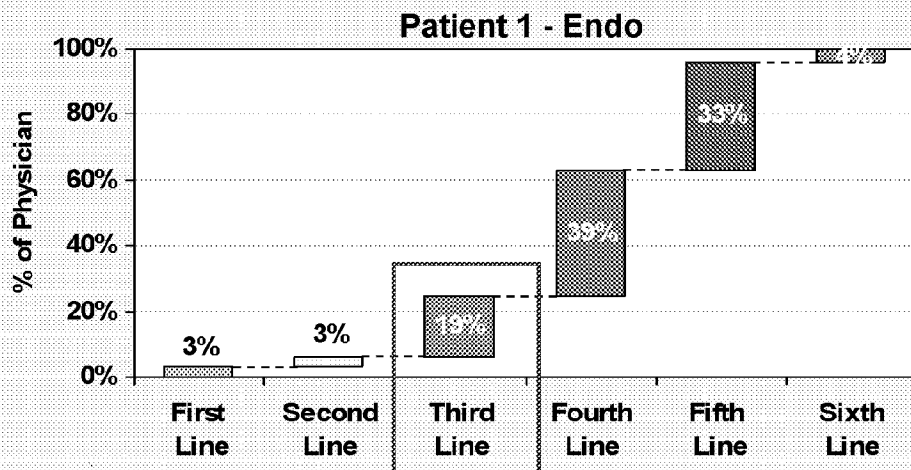
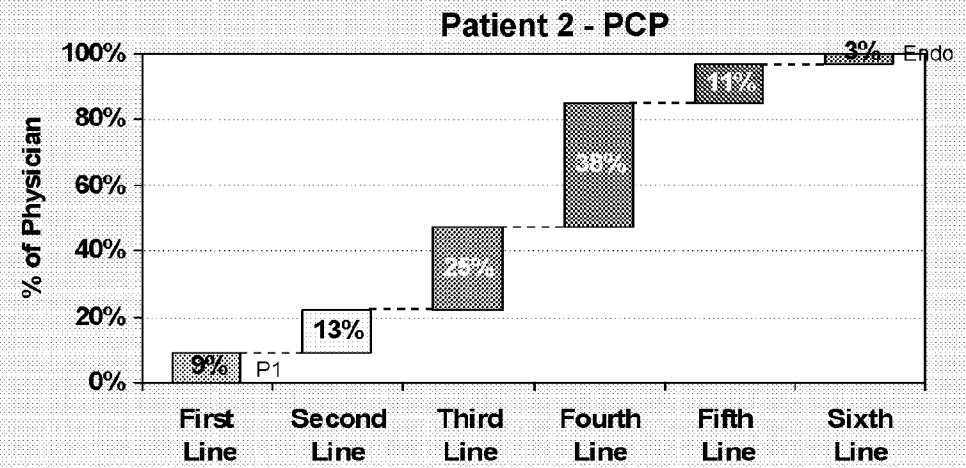
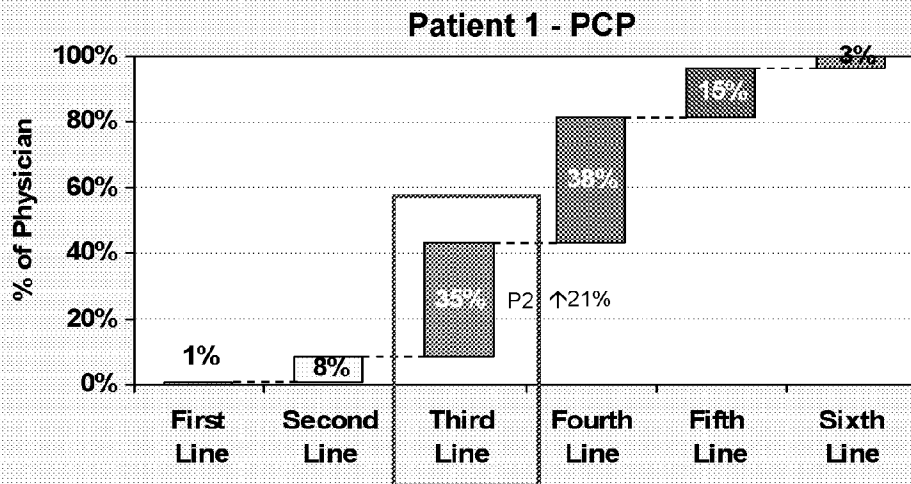
- ◆ Introduction
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When treating Patient 1, a higher percentage of PCPs than Endos initiate insulin by the third line of therapy; approximately 10% of physicians recommend insulin in the first line of therapy for Patient 2

Distribution of First Insulin Use: by Patient and Specialty



Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. Other therapies are removed from the treatment regimen in the waves following the addition of insulin. Statistically different at 95% between patients within a specialty as noted: P1 = Patient 1, P2 = Patient 2. Patient 1 profile revised Sep-Oct '07.

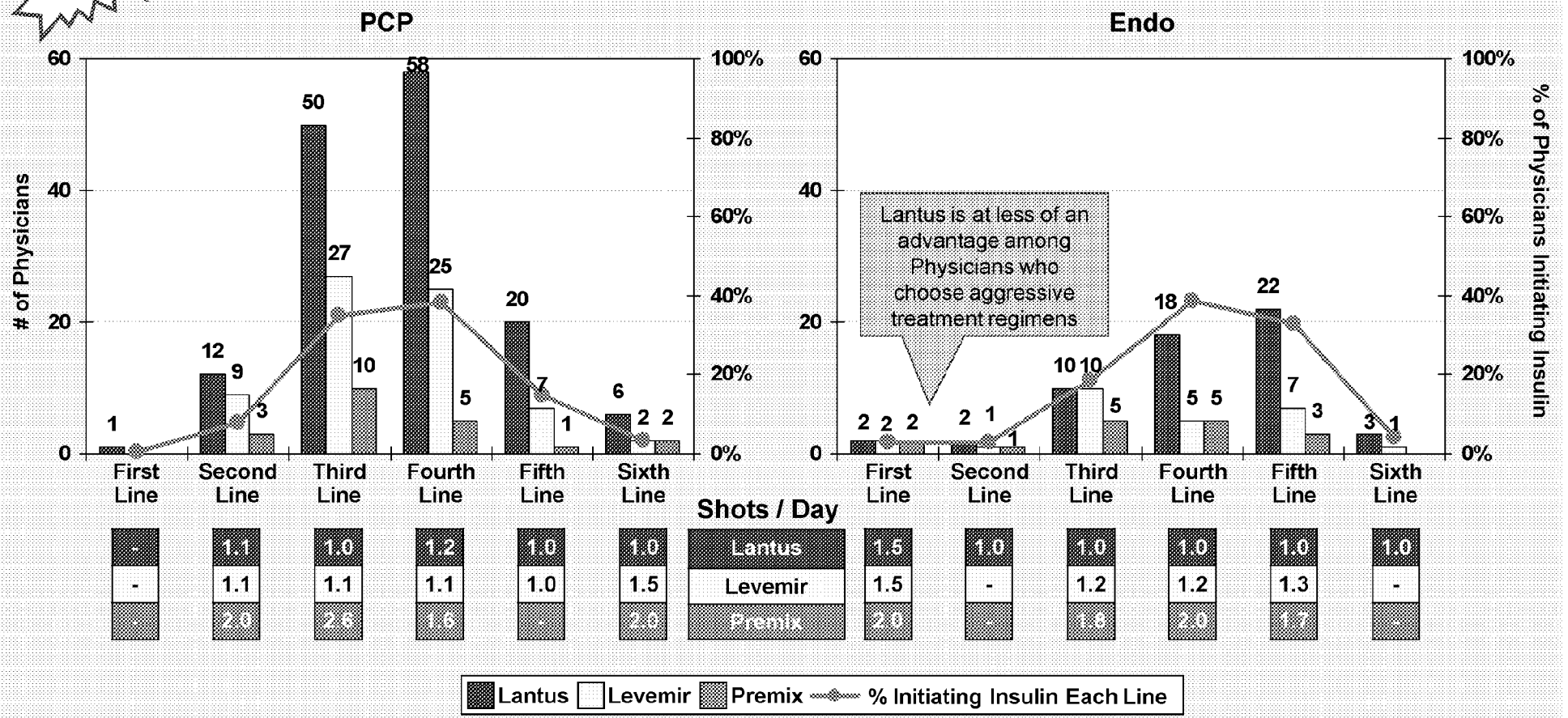
	PCP	Endo
P1	191	70
P2	189	85



In lines three and four, where insulin initiation is highest, the number of physicians recommending Lantus is more than double those recommending Levemir



Type of Insulin Initiated in Each Line of Therapy for Patient 1: by Specialty



Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Statistical testing between products within a line shown in appendix. Data assumes that once insulin is added to the treatment regimen, it remains in the regimen. Physicians able to select more than one kind of insulin in same line.

	2018	2019
P1	191	70
P2	189	85

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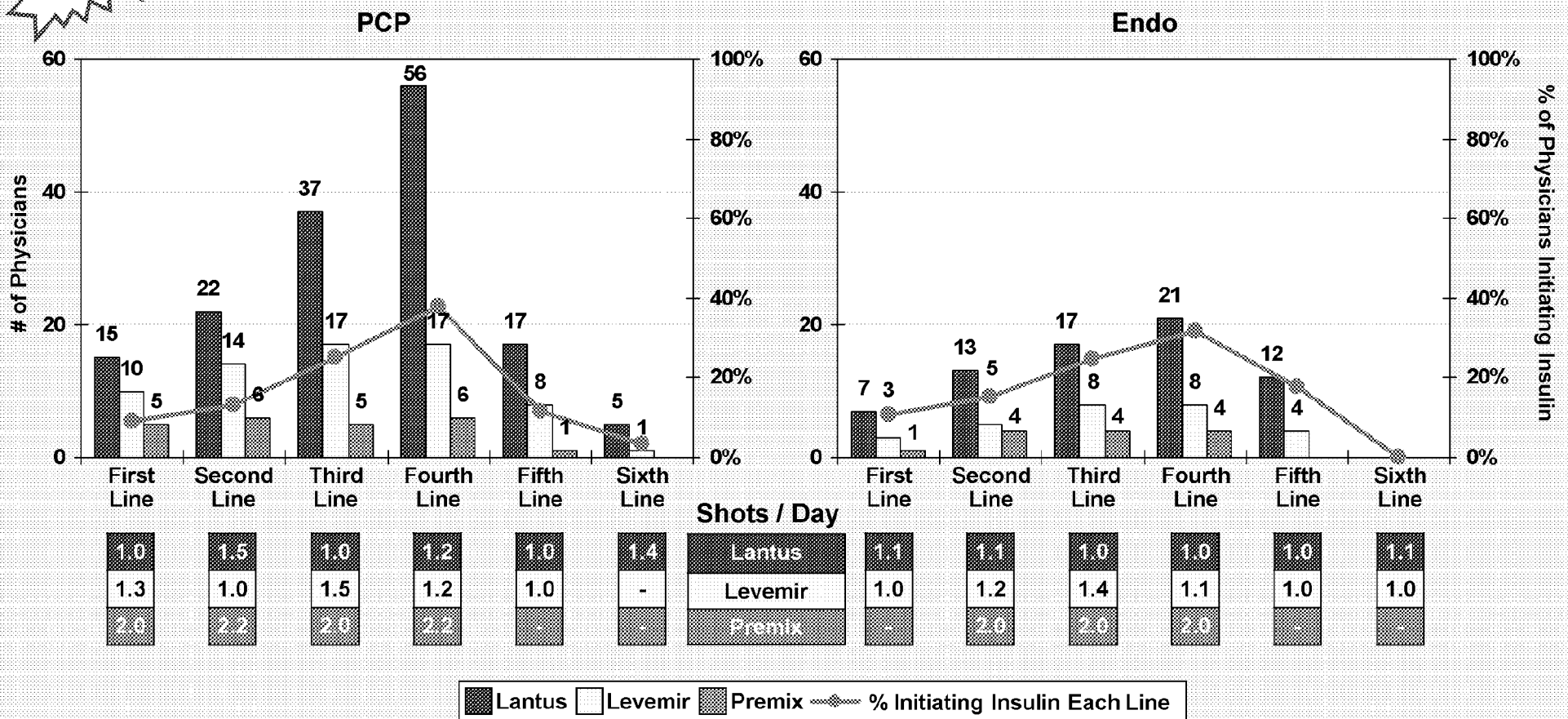
PTX-0739.0093
 Sanofi Exhibit 2146.093
 Mylan v. Sanofi
 IPR2018-01675



Similar to Patient 1, both PCPs and Endos initiate Lantus most often when selecting an insulin for Patient 2, across all lines of therapy



Type of Insulin Initiated in Each Line of Therapy for Patient 2: by Specialty



Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Statistical testing between products within a line shown in appendix. Data assumes that once insulin is added to the treatment regimen, it remains in the regimen. Physicians able to select more than one kind of insulin in same line.

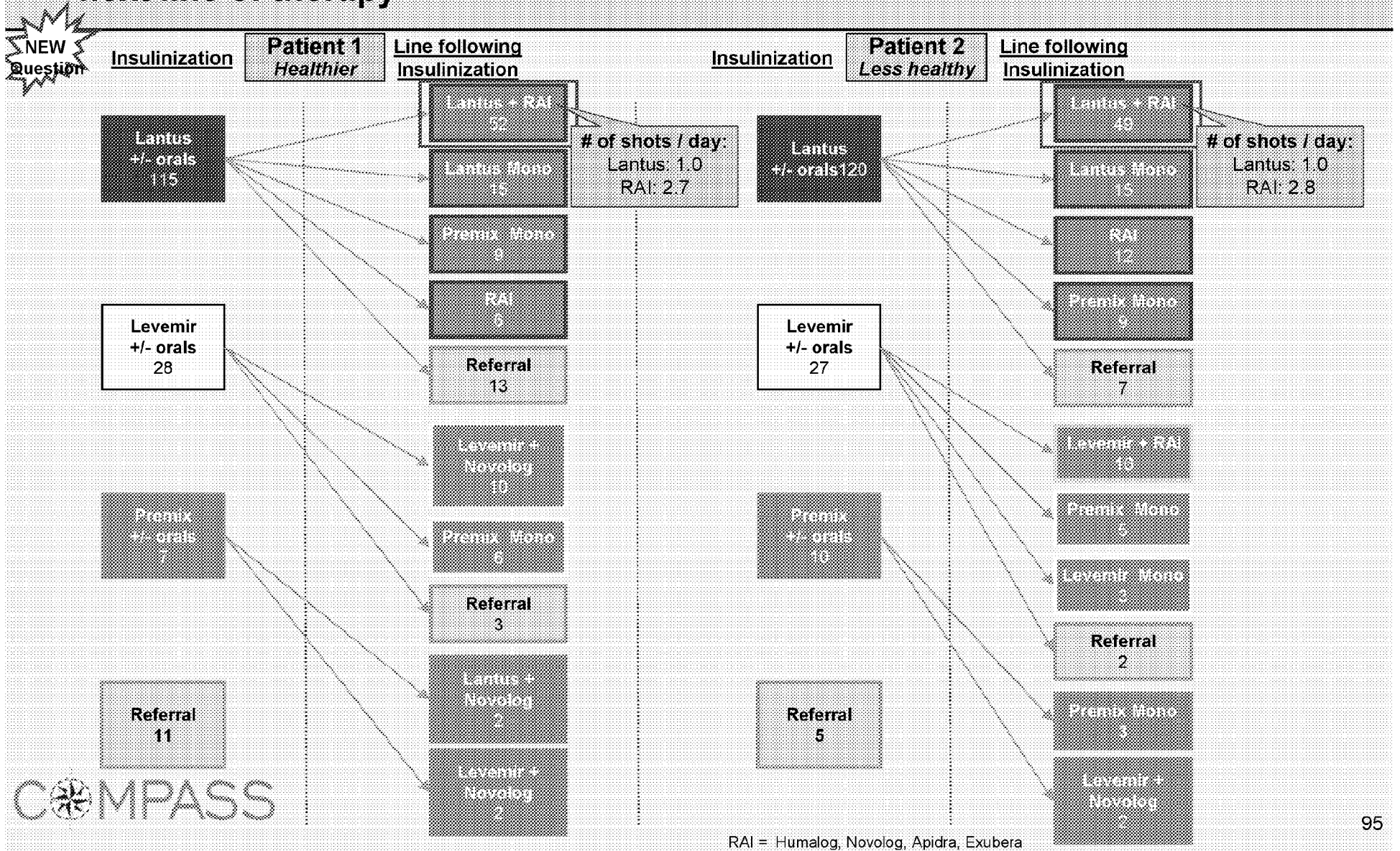
	2018	2019	Total
P1	191	70	94
P2	189	85	

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SANOFI3_90330900

PTX-0739.0094
 Sanofi Exhibit 2146.094
 Mylan v. Sanofi
 IPR2018-01675

Of those physicians who choose Lantus +/- orals upon insulinization, the largest number select Lantus in combination with a rapid acting insulin in the next line of therapy





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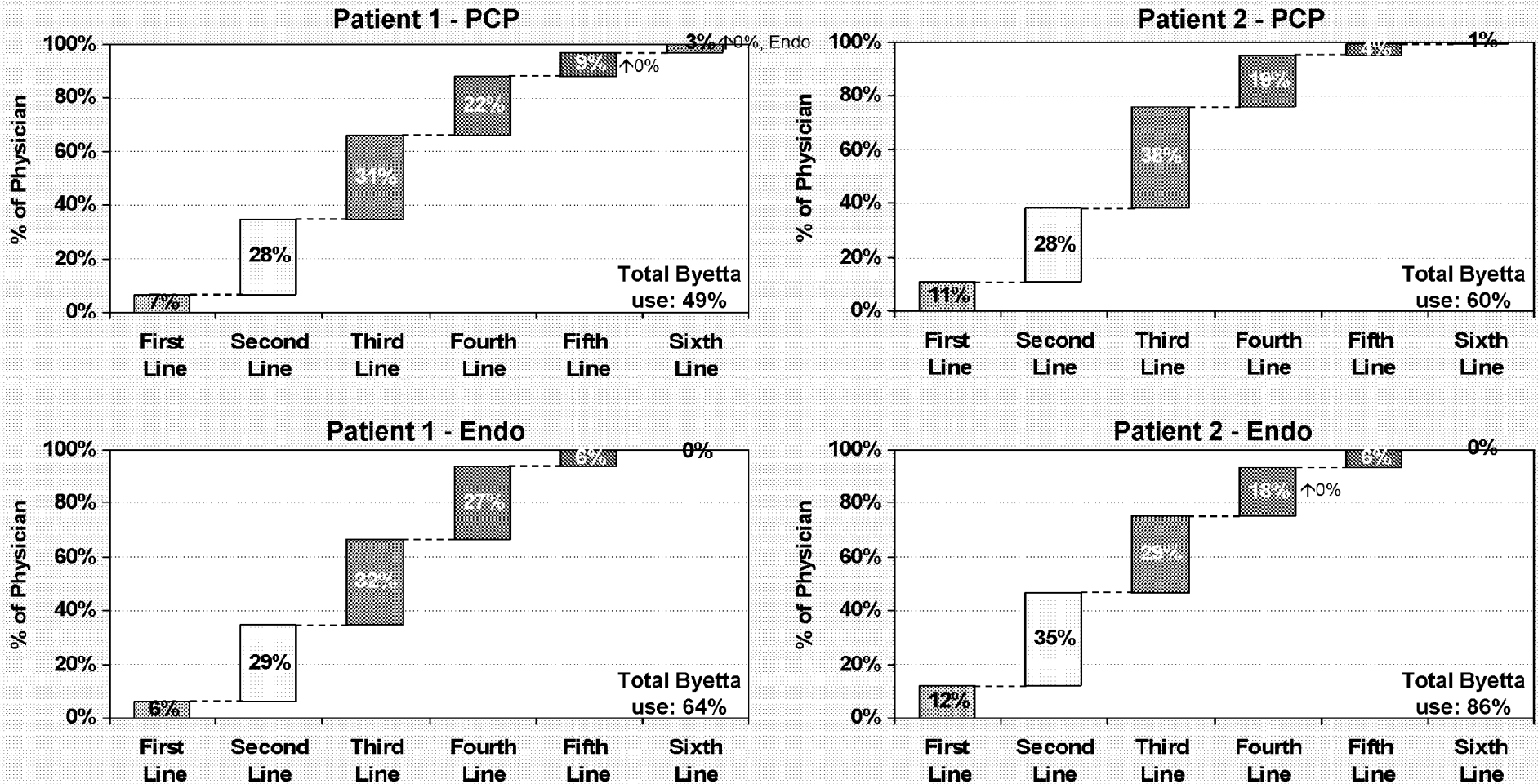
- ◆ Introduction
- ◆ Key Findings
- ◆ Awareness and Trial
- ◆ Special Topics
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The 86% of Endos who recommend Byetta for Patient 2 tend to initiate it earlier than PCPs; Endos are also more likely to use Byetta for Patient 1

Distribution of First Byetta Use: by Patient and Specialty



Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. Other therapies are removed from the treatment regimen in the waves following the addition of insulin. Statistically different at 95% between patients within a specialty as noted: P1 = Patient 1, P2 = Patient 2. Patient 1 profile revised Sep-Oct '07.

	PCP	Endo
P1	191	70
P2	189	85

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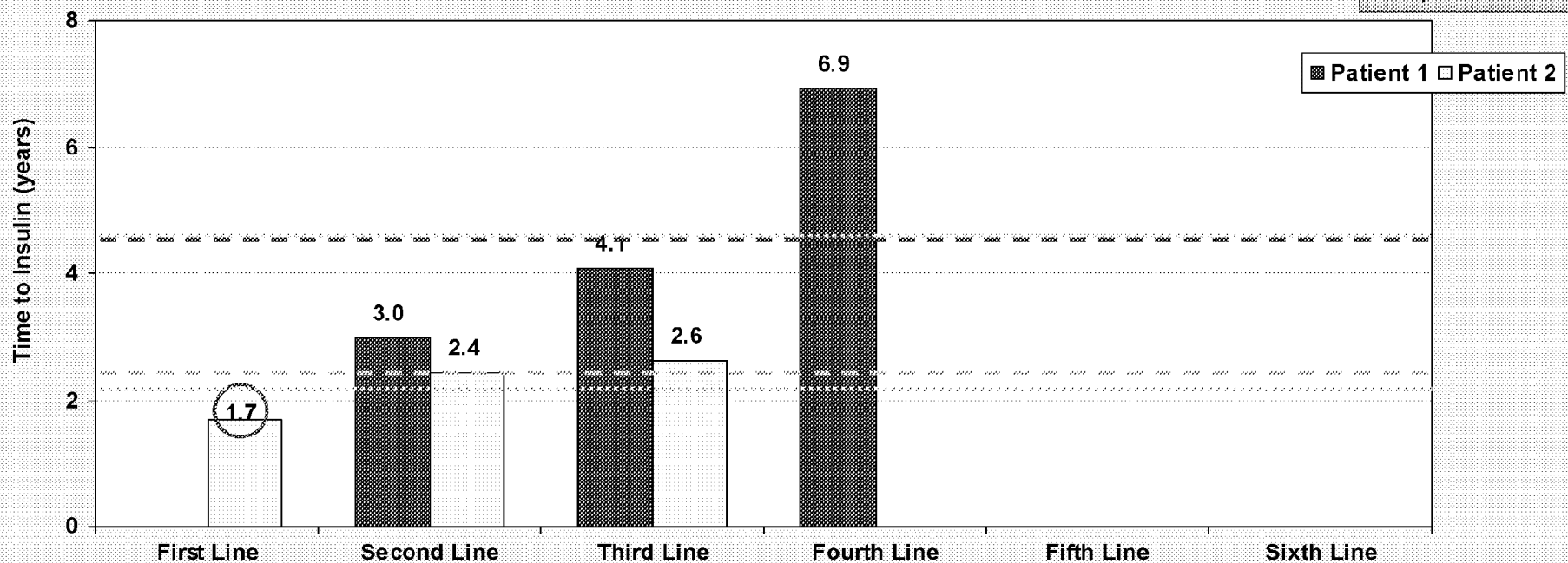
PTX-0739.0097
 Sanofi Exhibit 2146.097
 Mylan v. Sanofi
 IPR2018-01675



Physicians recommending Byetta as a first line treatment for Patient 2 initiate insulin after 1.7 years, faster than those who do not use Byetta

Time to Insulin (years) for Line of Therapy in which Byetta Is Added: by Patient Type

Note: n-sizes < 20 not plotted in chart



Patient 1 n=
Patient 2 n=

30

49
71

37
53

24

	Average time to Insulin	
	All Physicians	Byetta non-users
Patient 1
Patient 2

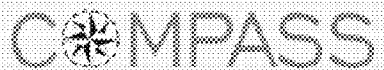
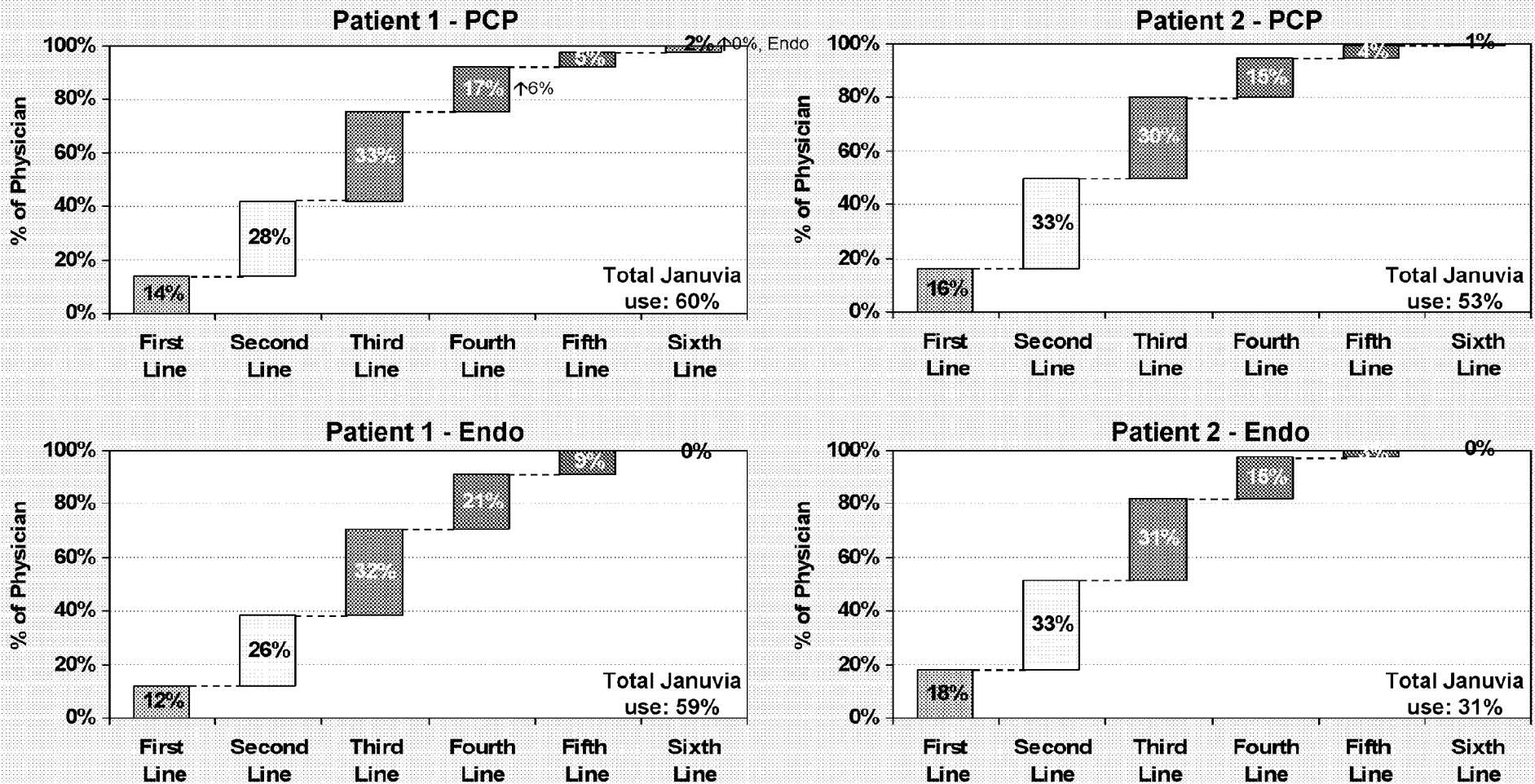


Source: COMPASS Sales Force Tracking Study
TXP: What would you recommend as each line of therapy? Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. TXP5-16: Length of time controlled on this therapy before switching to next therapy



Usage of Januvia for Patient 1 is nearly identical across specialties; however, 53% of PCPs recommend Januvia for Patient 2, versus 31% of Endos

Distribution of First Januvia Use: by Patient and Specialty



Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. Other therapies are removed from the treatment regimen in the waves following the addition of insulin. Statistically different at 95% between patients within a specialty as noted: P1 = Patient 1, P2 = Patient 2.

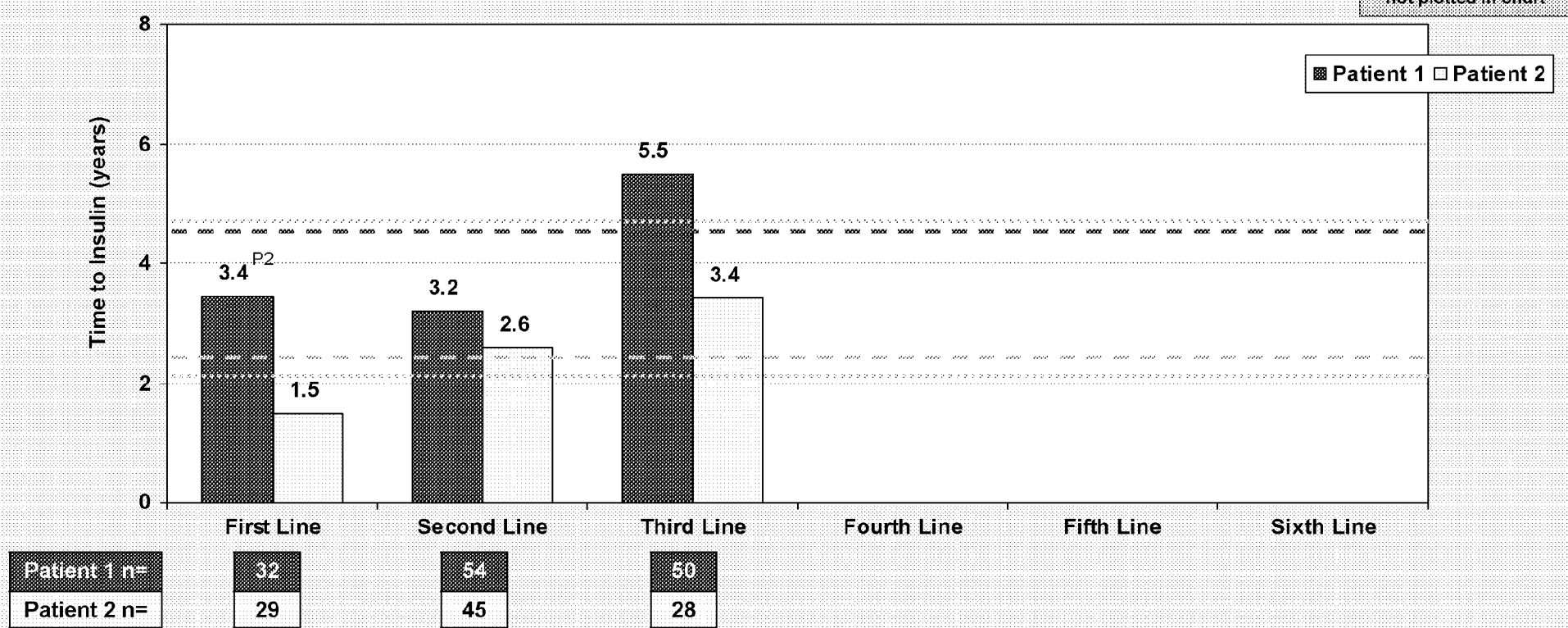
	99	85
P1	191	70
P2	189	85



When physicians add Januvia in the first two lines of therapy for Patient 1, insulinization occurs sooner than average

Time to Insulin (years) for Line of Therapy in which Januvia Is Added: by Patient Type

Note: n-sizes < 20 not plotted in chart



Average time to Insulin		
	All Physicians	Januvia non-users
Patient 1
Patient 2

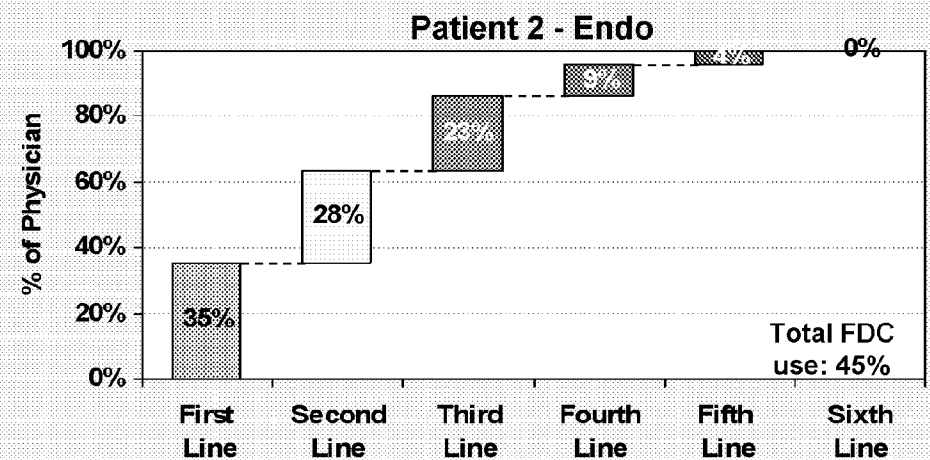
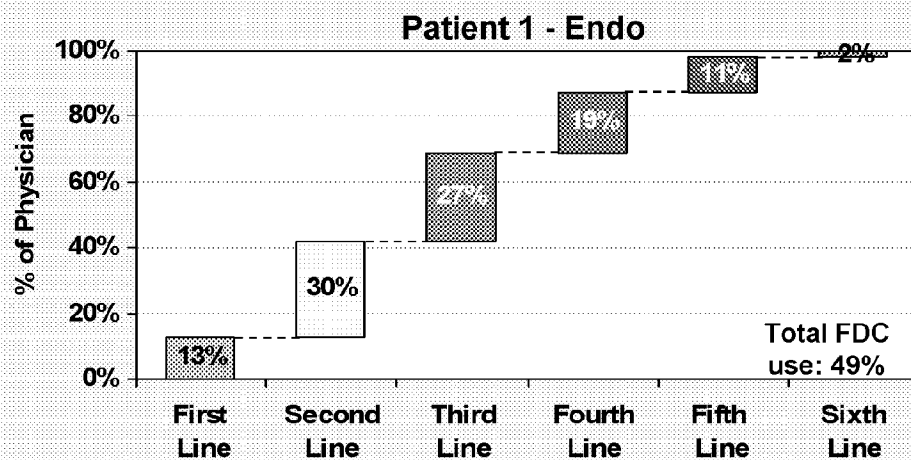
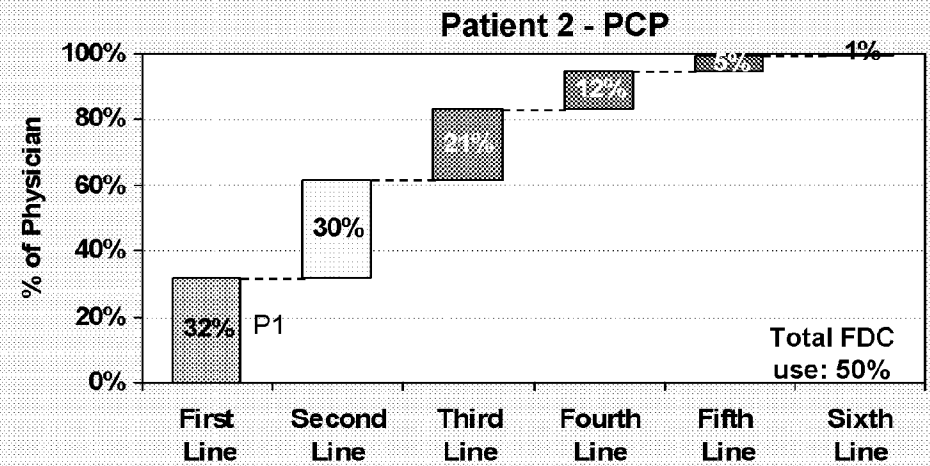
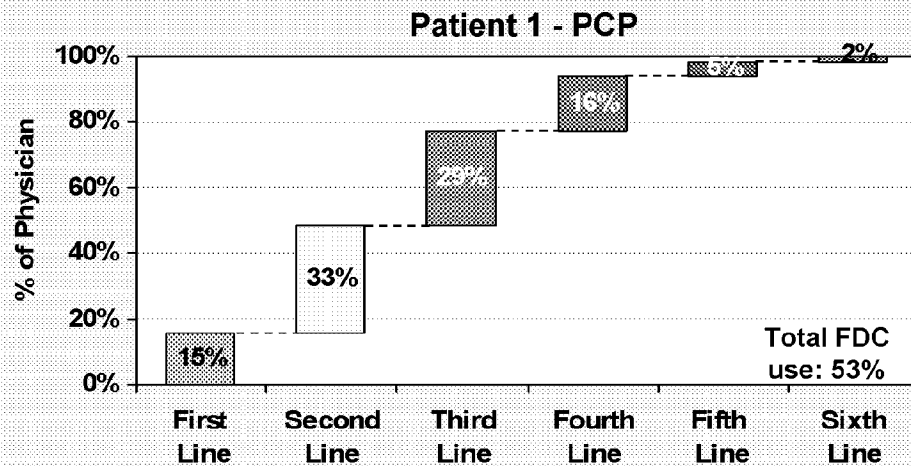


Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. TXP5-16: Length of time controlled on this therapy before switching to next therapy



The physicians who initiate Patient 2 on FDCs tend to recommend it earlier than those treating Patient 1; overall FDC use is similar across patients and specialties

Distribution of First FDC Use: by Patient and Specialty



Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. Other therapies are removed from the treatment regimen in the waves following the addition of insulin. Statistically different at 95% between patients within a specialty as noted: P1 = Patient 1, P2 = Patient 2.

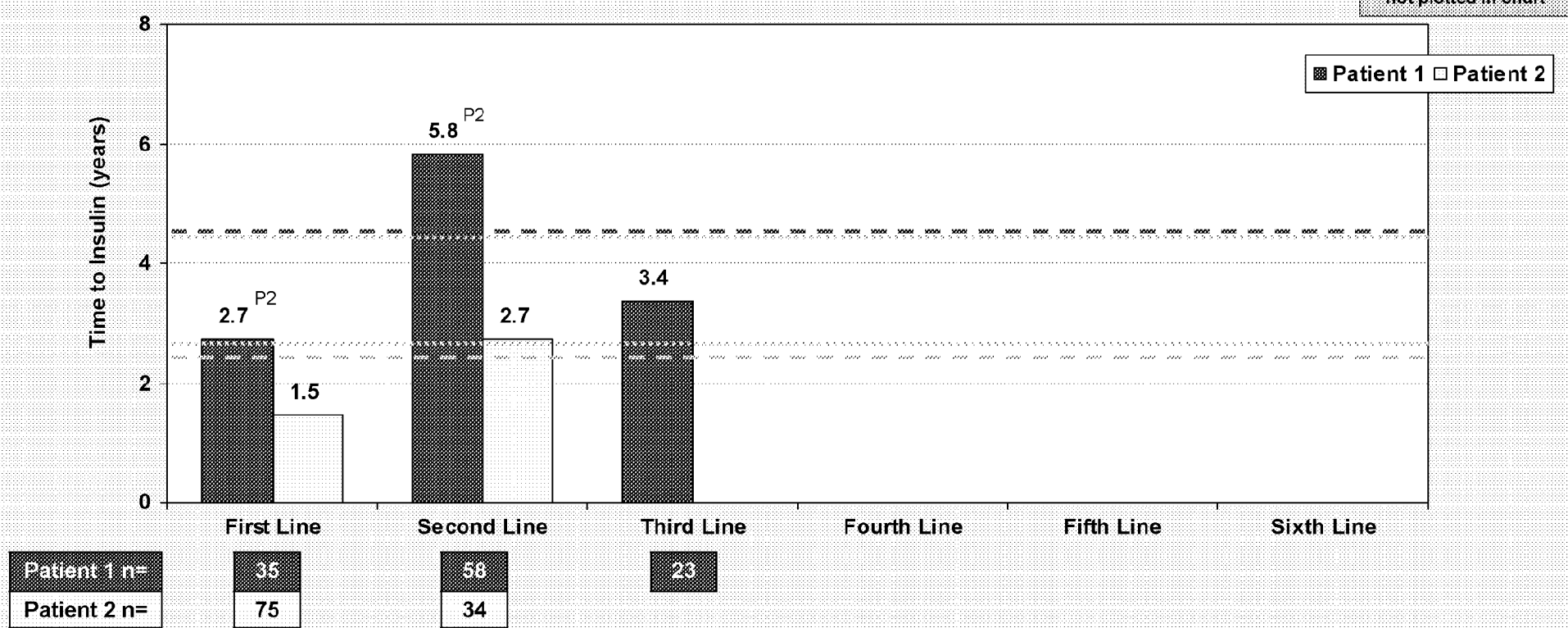
	191	70	101
P1	189	85	
P2			



For patients placed on fixed dose combinations in the first line of therapy, insulinization occurs sooner than the overall average

Time to Insulin (years) for Line of Therapy in which FDCs Are Added: by Patient Type

Note: n-sizes < 20 not plotted in chart



Average time to Insulin		
	All Physicians	FDCs non-users
Patient 1
Patient 2

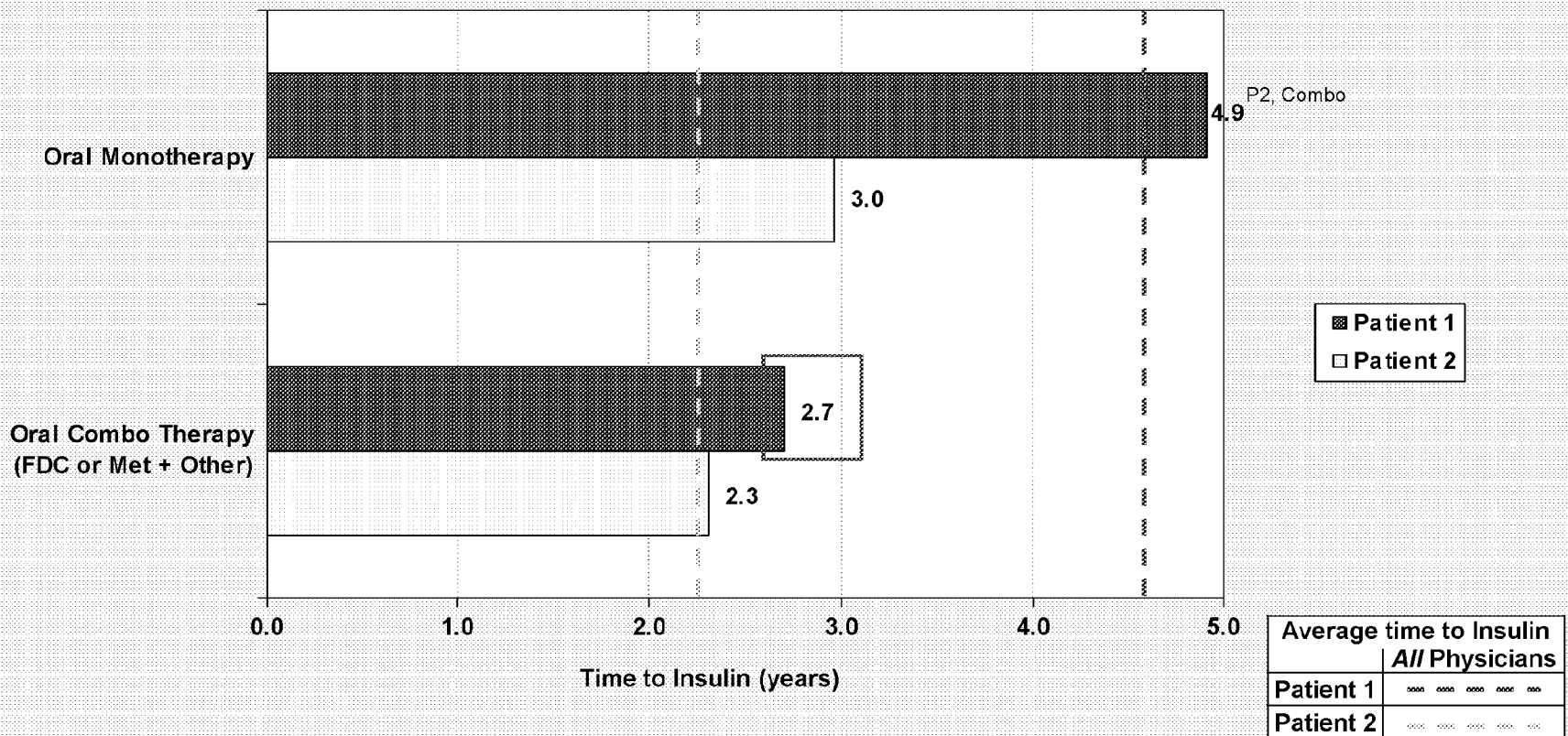


Source: COMPASS Sales Force Tracking Study
 TXP: What would you recommend as each line of therapy? Note: Data assumes that once insulin is added to the treatment regimen, it remains in the regimen through the sixth line. TXP5-16: Length of time controlled on this therapy before switching to next therapy



For Patient 1, use of FDCs or Metformin in combination with other orals in the first line of therapy leads to insulinization significantly sooner – 2 years sooner - than oral monotherapy

Time to Insulin (years) by Type of Therapy Initiated in *First Line*: by Patient Type



	Average time to Insulin	
	All Physicians	
Patient 1	○○○ ○○○ ○○○ ○○○ ○○○	
Patient 2	○○○ ○○○ ○○○ ○○○ ○○○	



Source: COMPASS Physician ATU Tracking Study. Note: Data are weighted by physician population. Statistically different at 95% between prescribing change as noted in data labels. Not statistically different at 95% between specialties. T2D6: How has the Avandia news affected your prescribing habits for new patients? T2D6B.C: By what percent have you reduced your new prescriptions written for [Avandia / Avandamet / Avandaryl], [Actos / ACTOplus Met / Duetact]?

	Sep 08-07	
	P1	P2
Mono	186	116
FDC/Met	60	108
+Other		

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SANOI13_90330909



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Unaided, 28% of physicians recall discussing the SoloSTAR pen with their Lantus reps; weight-related messages are the most commonly recalled among Levemir and Byetta visits

Unaided Message Recall (Main Message): Total

(% of physicians recalling)

sanofi-aventis for Lantus

Main Message	May – Jul '06	Mar – Apr '07	Sep – Oct '07
SoloSTAR / New pen	0%	0%	28%
General efficacy	26%	18%	23%
Duration of action / 24 hour	48%	39%	22%
QD dosing / Once daily	6%	13%	19%
Glucose / HbA1c control	0%	9%	9%
n =	109	127	126

Amylin or Eli Lilly for Byetta

Main Message	May – Jun '06	Mar – Apr '07	Sep – Oct '07
Weight loss / No weight gain	49%	47%	48%
Glucose / HbA1c control	8%	29%	27%
General efficacy	41%	15%	21%
Safety / Tolerability	4%	12%	11%
Use Byetta early in treatment	0%	0%	10%
n =	107	128	118

Novo Nordisk for Levemir

Main Message	May – Jul '06*	Mar – Apr '07	Sep – Oct '07
Less weight gain	13%	21%	33%
Duration of action / 24 hour	1%	46%	27%
Comparison to Lantus	13%	19%	18%
General efficacy	11%	18%	18%
QD dosing / Once daily	14%	11%	17%
n =	110	122	126

Merck for Januvia

Main Message	May – Jul '06	Mar – Apr '07	Sep – Oct '07
General efficacy	-	30%	30%
Safety / Tolerability	-	23%	22%
Glucose / HbA1c control	-	9%	17%
Weight loss / No weight gain	-	3%	14%
Combination therapy	-	11%	13%
n =	-	126	104



Source: COMPASS Sales Force Tracking Study Note: Data are weighted by reach. Weighted percent of physicians shown for open-ended questions. ME1: In your last discussion with your [company] sales representative, what was the main message conveyed regarding [product]? This message could be something your sales representative brought up during the detail or in response to a question that you asked the representative. Please be as specific as possible. *Responses in May-Jul '06 for all Novo Insulins. 105



Efficacy and glucose control messages are among those most frequently discussed by Humalog and Novolog Premix reps

Unaided Message Recall (Main Message): Total
(% of physicians recalling)

Eli Lilly for Humalog Mix

Main Message	May – Jul '06	Mar – Apr '07	Sep – Oct '07
Glucose / HbA1c control	0%	13%	21%
PPG control	17%	9%	18%
General efficacy	36%	23%	17%
Convenience / Ease of use	6%	20%	14%
Uses of Humalog 50/50	23%	7%	11%
n =	102	124	103

Novo Nordisk for Novolog 70/30

Main Message	May – Jul '06*	Mar – Apr '07	Sep – Oct '07
General efficacy	11%	18%	27%
Cost / Formulary status	10%	21%	20%
PPG control	0%	12%	16%
Dosing / Titration	3%	5%	13%
Convenience / Ease of use	3%	17%	13%
n =	110	127	105

Source: COMPASS Sales Force Tracking Study

Note: Data are weighted by reach. Weighted percent of physicians shown for open-ended questions. ME1: In your last discussion with your [company] sales representative, what was the main message conveyed regarding [product]? This message could be something your sales representative brought up during the detail or in response to a question that you asked the representative. Please be as specific as possible.

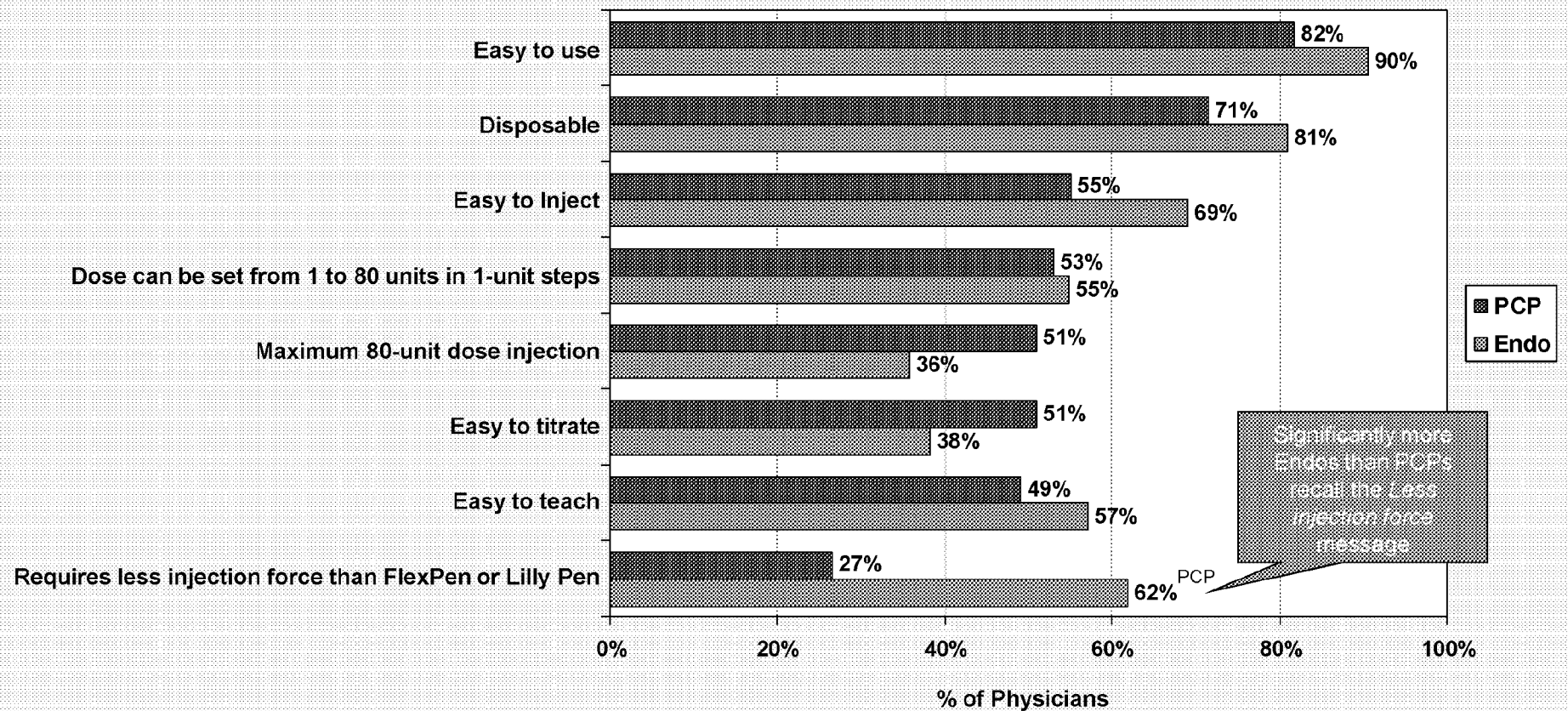
*Responses in May-Jul '06 for all Novo Insulins.





>50% of physicians detailed on SoloSTAR recalled hearing 6 out of 8 discussion topics related to SoloSTAR

SoloSTAR Discussion Topics: by Specialty



Source: COMPASS Sales Force Tracking Study

Note: Data are weighted by reach. Statistically different at 95% between specialties as noted. ME6S2: Please indicate which of the following product attributes or topics you discussed with your sanofi-aventis sales representative about the SoloSTAR pen device.

Sep-Oct 07	
PCP	49
Endo	42

07



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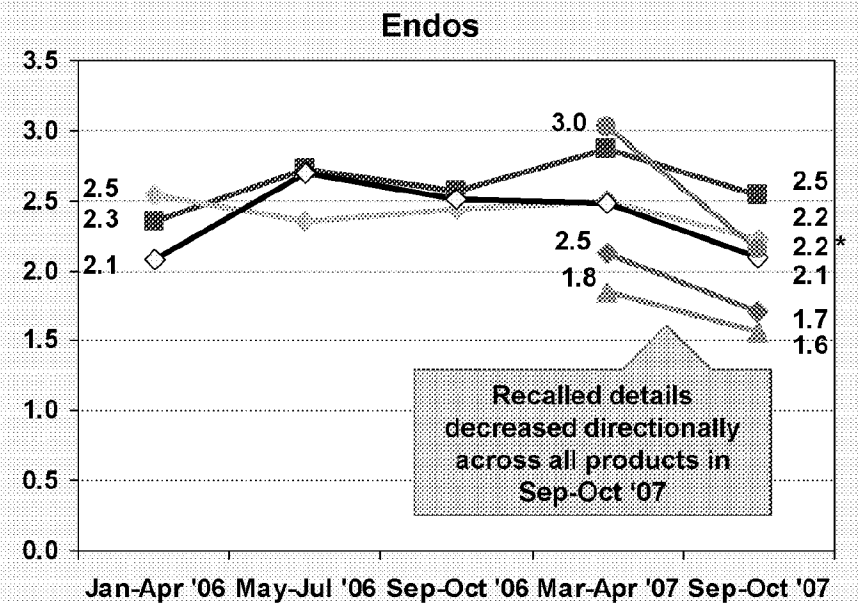
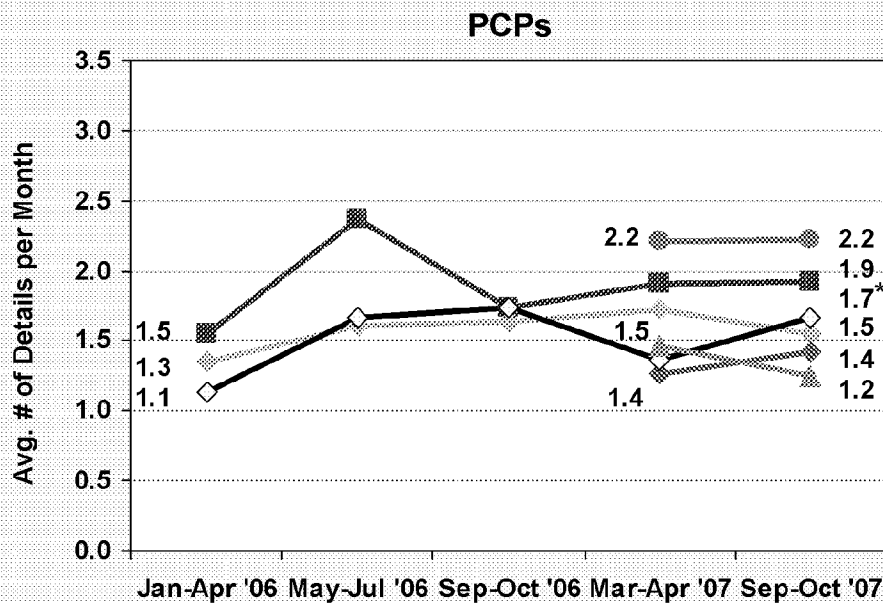
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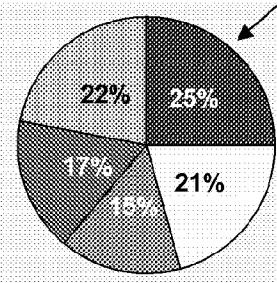
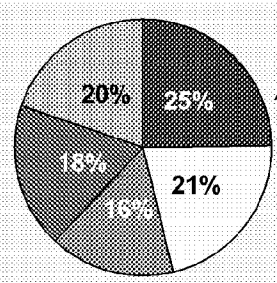
In Sep-Oct '07, PCPs and Endos report a 25% share of voice for Lantus among select insulins and Byetta; Levemir detail recall increased among PCPs and decreased among Endos

Recalled Number of Product Details in the Past Month: by Specialty



Recalled details decreased directionally across all products in Sep-Oct '07

Share of voice among select insulins and Byetta



Source: COMPASS Physician Study
 Note: Data are weighted by physician population. Statistical testing between products shown in appendix. BS4: In the past month, how many times has a sales representative visited you to inform you about each of the following products? Data are recalled details, not actual PDEs.

Sep-Oct '07	
PCP	125
Endo	76

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PTX-0739.0109
 Sanofi Exhibit 2146.109
 Mylan v. Sanofi
 IPR2018-01675



PCPs recall the longest details and highest percentage of new learnings from Levemir reps

Detail Characteristics: PCP

	Rep Relationship (years)	Length of Detail (minutes)	% Dialogue Discussions	Detail Location	% Learning something new	New Learnings (% of MDs learning something new)
Lantus	2.5	6.2	63%	34% Hallway 22% Lunch/Break room 21% Personal office	30%	74% New pen 13% SS is disposable 9% Formulary update
Levemir	1.7	10.1	63%	37% Lunch/Break room 29% Hallway 18% Personal office	33%	16% Smooth action 16% Formulary update 16% Less weight gain
Byetta	1.6	8.3	67%	29% Lunch/Break room 28% Hallway 23% Personal office	15%	44% Formulary update 11% Tolerability 6% Indication update
Humalog Mix	2.6	6.4	47%	39% Hallway 21% Personal office 20% Lunch/Break room	24%	36% Humalog 50/50 27% Dosing / Titration 18% Formulary update
Novolog 70/30	2.1	6.8	59%	30% Hallway 29% Lunch/Break room 18% Personal office Endo	11%	25% Formulary update 25% Efficacy / Features 13% Dosing / Titration
Januvia	2.2	6.6	63%	33% Hallway 28% Personal office 25% Lunch/Break room	19% ^{↓32%}	21% Formulary update 21% Dosing / Titration 14% Safety/side effects



New Learnings percentages not mutually exclusive. Other footnotes shown in appendix

Yellow shading indicates category leader

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Over one-quarter of Endos learned something new in their most recent Lantus detail – a large majority of those new insights involve SoloSTAR

Detail Characteristics: Endo

	Rep Relationship (years)	Length of Detail (minutes)	% Dialogue Discussions	Detail Location	% Learning something new	New Learnings (% of MDs learning something new)
Lantus	3.0	7.1	72%	48% Personal office 24% Lunch/Break room 16% Hallway	26%	92% New pen 39% SoloSTAR info 15% Formulary update
Levemir	1.9	7.8	70%	40% Lunch/Break room 28% Hallway 20% Personal office	16%	25% New needles 13% Less variability 13% Dosing / Titration
Byetta	2.4 ^{PCP}	8.6	84%	30% Lunch/Break room 23% Hallway 21% Personal office	7%	38% New long-acting product out soon 13% Formulary update
Humalog Mix	3.2	9.4	50%	32% Hallway 29% Personal office 25% Lunch/Break room	19%	50% Lily interested in inhaled insulin 50% Education opport.
Novolog 70/30	2.6	4.7	45%	34% Hallway 24% Personal office 21% Lunch/Break room	7%	50% Starter Kit / Coupons 50% Pen device
Januvia	1.8	9.7	66%	34% Personal office 31% Hallway 17% Lunch/Break room	17%	40% Formulary update 20% Vouchers 20% Indication update



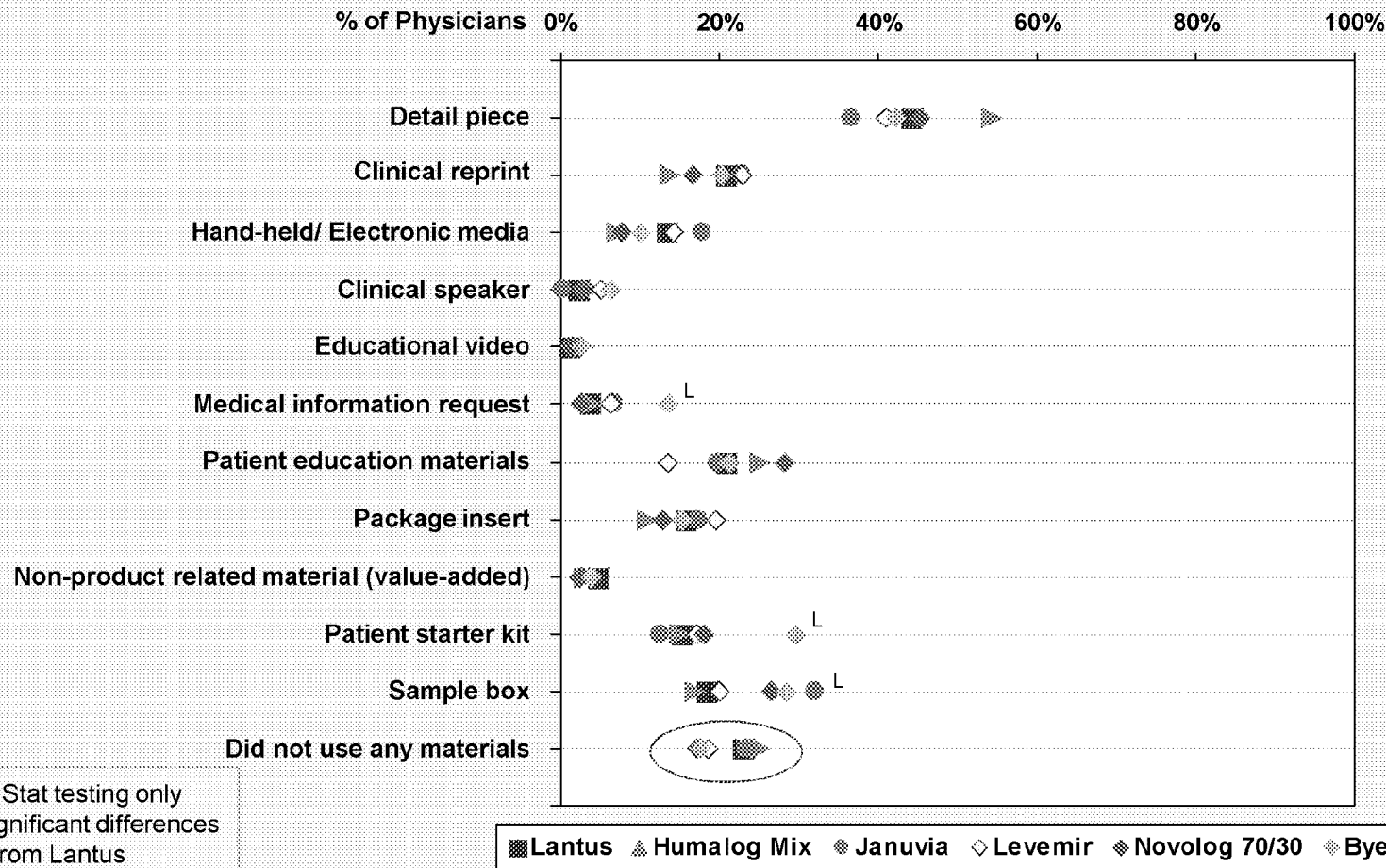
New Learnings percentages not mutually exclusive. Other footnotes shown in appendix

Yellow shading indicates category leader



Use of the various sales rep resources differs marginally by company; one-quarter of physicians were not shown any materials in their last Lantus detail

Resources Sales Rep Used in Last Discussion: Total



Note: Stat testing only shows significant differences from Lantus

Sep-Oct 07	
Lantus	126
Levemir	126
Byetta	118
Hum Mix	103
Nov 70/30	105
Januvia	104

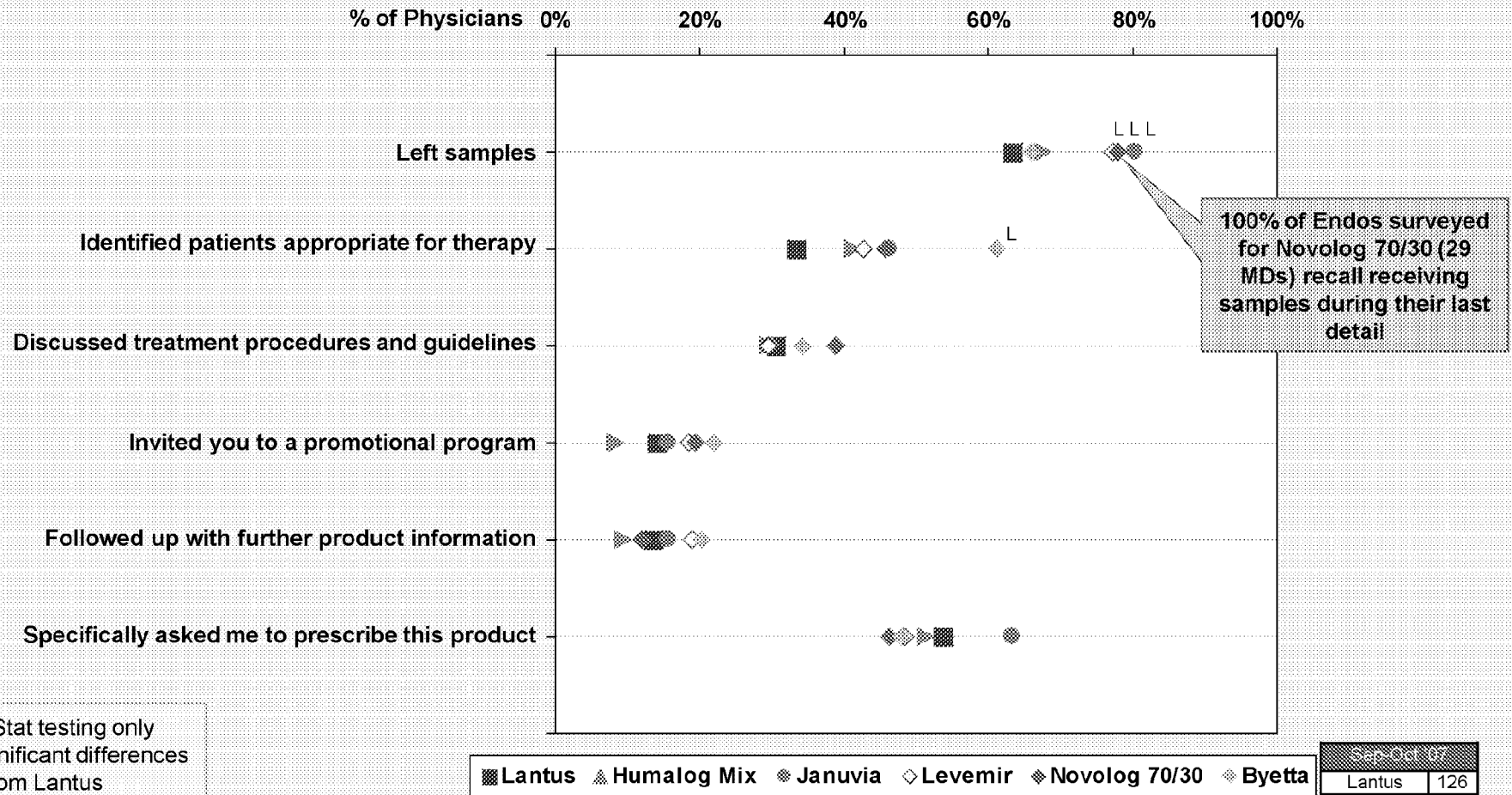


Source: COMPASS Sales Force Tracking Study
 Note: Data are weighted by reach. L=Statistically different at 95% between Lantus and other products. TRK6: During the last detail for [Product] what did the sales rep use to aid the discussion?



Directionally, Lantus reps leave samples and identify patients appropriate for therapy less often than do competitor reps

Activities Sales Rep Performed During Last Discussion: Total



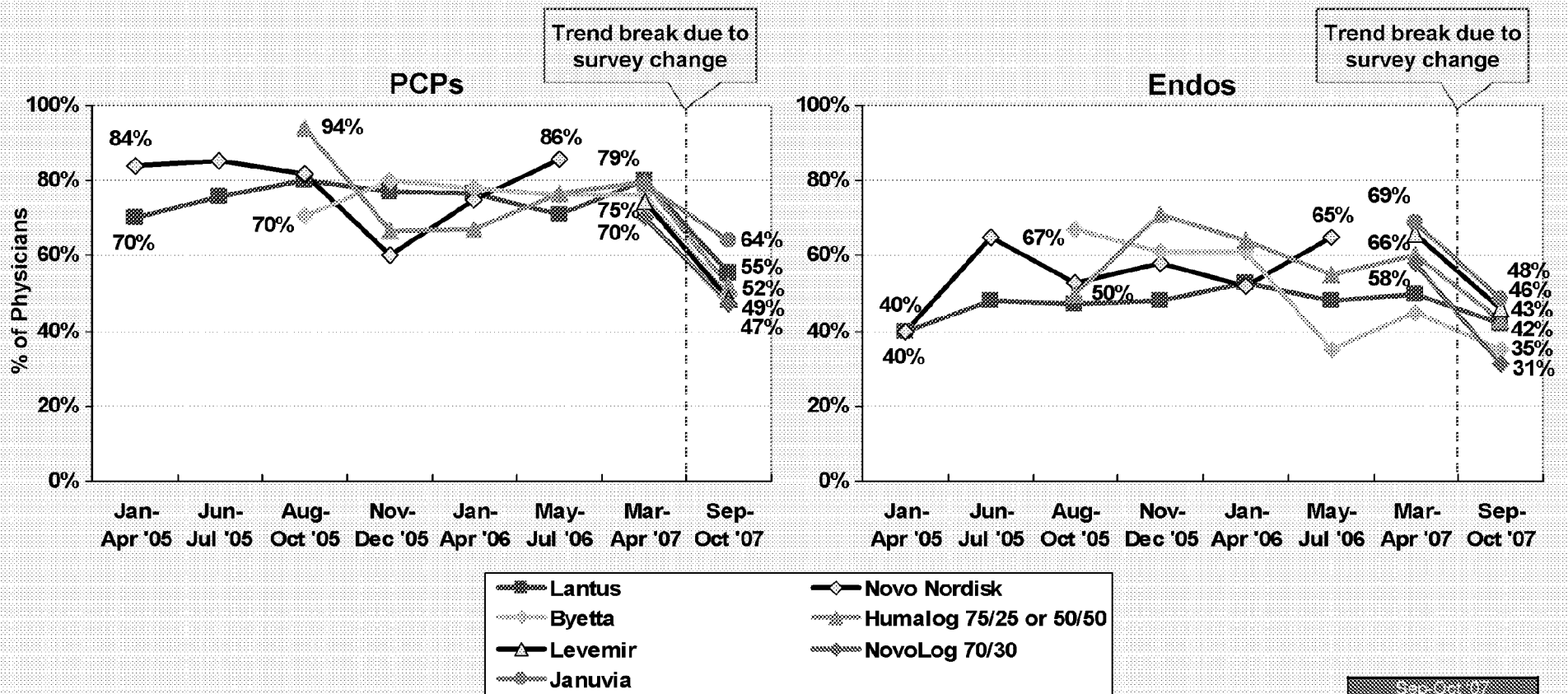
Source: COMPASS Sales Force Tracking Study

Note: Data are weighted by reach. L=Statistically different at 95% between Lantus and other products. SFACT3: During the most recent detail for [Product], which of the following activities did the representative do?



Lantus reps “closed the call” directionally more often with PCPs than Endos in Sep-Oct '07, but there was a trendbreak in the data due to a necessary survey change that syncs Lantus up with COMPASS for other s-a brands

Physicians Specifically Asked to Prescribe: by Specialty



Specialty	Sep-Oct '07	
	PCP	Endo
Lantus	76	50
Levemir	76	50
Byetta	75	43
Hum Mix	75	28
Nov 70/30	76	29
Januvia	75	29

Source: COMPASS Sales Force Tracking Study
 Note: Data are weighted by reach. Dotted red line indicates trend break due to survey revisions for Sep-Oct '07. Green line formerly Eli Lilly Insulins. Not statistically different at between specialties. Statistical testing between product shown in appendix. Statistical testing not performed between Mar-Apr '07 and Sep-Oct '07 due survey revisions in Sep-Oct '07. LAN8: During your last visit from your [company] sales representative for [product], did the representative specifically ask you to prescribe the product?



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PTX-0739.0114
 Sanofi Exhibit 2146.114
 Mylan v. Sanofi
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