Understanding Customer Feedback on the Tapentadol Immediate Release Oral Tablets C-II Dossier

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BACKGROUND

- Health plans and health-care institutions emphasize evidence-based medicine as well as the cost-effectiveness of a product to make formulary decisions. A standardized dossier format allows manufacturers to respond to product information requests with a comprehensive document that includes background, efficacy, safety, and the economic value of a product.
- There are a few formats available that manufacturers can use to prepare a dossier such as Academy of Managed Care Pharmacy (AMCP)2, WellPoint3, and Drug Effectiveness Review Project (DERP)4.
- The tapentadol IR oral tablets C-II dossier was developed based on the AMCP
- Ortho-McNeil Janssen Scientific Affairs, LLC (OMJSA) organized a tapentadol IR oral tablets C-II dossier Advisory Board which consisted of 11 advisors from institution-focused or managed-care focused areas.⁵ Prior to the meeting, a premeeting internet survey was sent and completed by the advisors.
- On Friday, March 6th 2009, the Advisory Board was convened with the objective to obtain feedback on the presentation of data in a draft dossier from a panel of pharmacists involved in formulary decision-making and who represent the opinions of the customers who would request a dossier. The goal was to develop a fair-balanced and useful dossier.
- Feedback consisted of formatting changes to provide a more concise dossier as well as to improve clarity.
- The dossier was revised and finalized. Tapentadol IR was launched on June 22nd 2009 and the dossier was made available to customers.

OBJECTIVE

Evaluate feedback from our customers regarding the flow, format, and content of the tapentadol IR oral tablets C-II dossier

METHODS

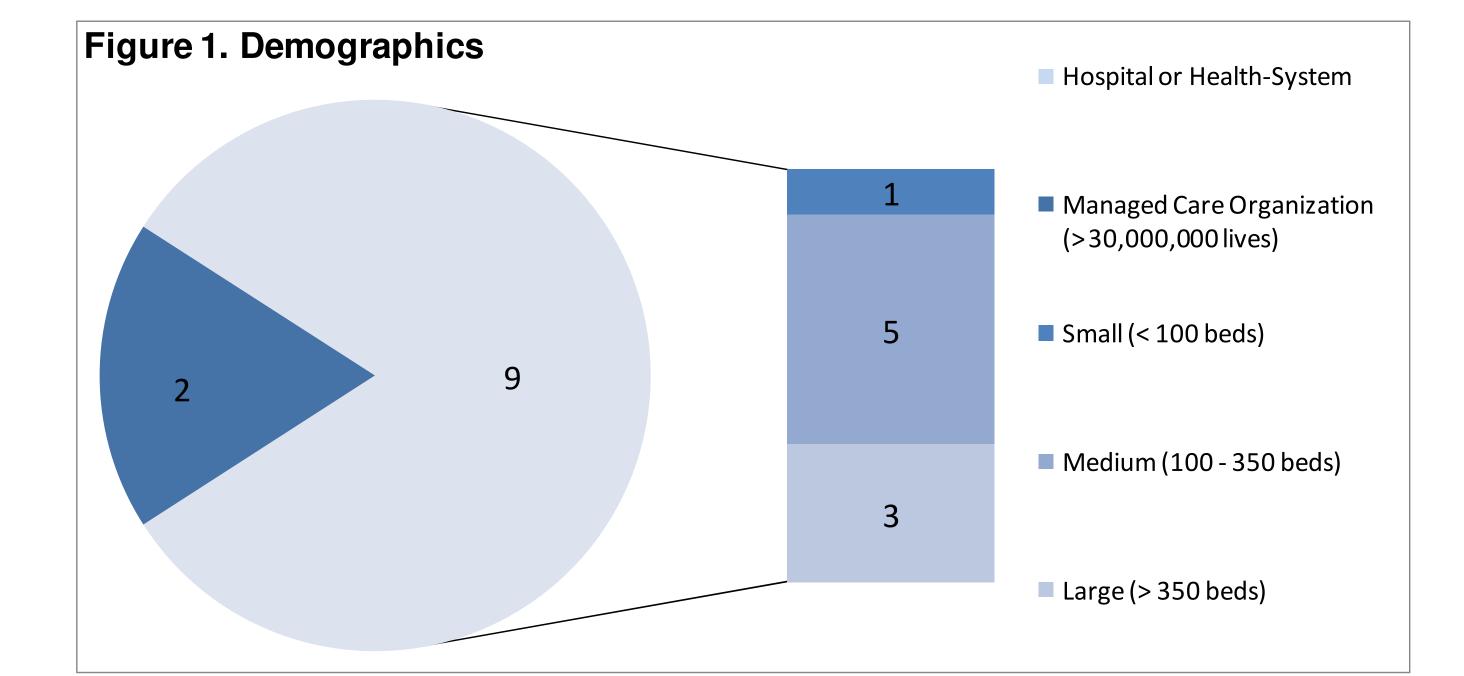
- An anonymous survey containing 19 questions was sent via email to 181 customers who submitted unsolicited requests for the dossier from product launch date (June 22nd) to sixteen weeks post-launch (October 12th) in 2009
- Dossier recipients were identified via Siebel and only those who provided an email address were contacted
- Siebel® is a customer relationship management database
- Customers were given 2 weeks to respond

Survey Questions

- The survey contained 19 questions that assessed demographics as well as whether the dossier has met our customers' informational need based on *flow*. format, and content
- All respondents answered 3 demographic questions
- 1 Q assessed the purpose for which the dossier was requested
- 1 Q assessed flow
- 2 Q assessed <u>format</u>
- 1 Q branched into 3 Q
- 7 Q assessed content 1 Q branched into 6 Q
- Additional questions asked which section(s) of the dossier the customer would consider distributing to staff for their educational or product review awareness; opinions regarding the inclusion of additional information in the Supporting Clinical and Economic Information section; opinions regarding the inclusion of reprints and posters; strengths/weaknesses of the dossier
- Customers responded using a five-point likert scale as well as free text

RESULTS: Demographics

- Out of the 181 emails that went out to customers who submitted unsolicited requests for the tapentadol IR dossier, 167 reached the customer
- Eleven customers submitted results, 8 of whom completed the entire survey
- All 11 respondents are pharmacists
- Six hospitals or health-systems used the dossier as a main source of information. Both MCOs and 3 of the hospitals or health-systems used the dossier as a supplemental source of information.



RESULTS: Flow

Figure 2. Flow*

FLOW (Questions = 1)		Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Not Answered
Hospital or Health- System	Small (n= 1)	100%					
	Medium (n=5)	20%	80%				
	Large (n=3)	33%		67%			
Managed Care Organization (n=2)			100%				

- *Total # of responses for hospital or health-system: small=1; medium=5; large=3. Total # of responses for MCO=2. • For small hospitals or health-systems, medium hospitals or health-systems, and MCOs, the overall response was positive and customers were satisfied in reference to flow.
- For large hospitals or health-systems, 2 customers were neutral about the <u>flow</u>. The third customer was positive and satisfied.

RESULTS: Format

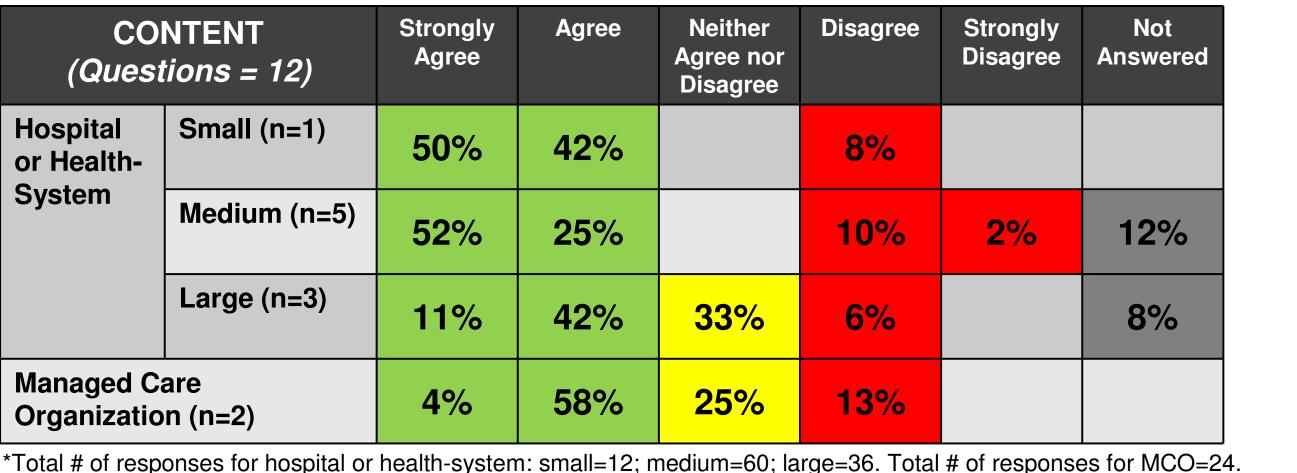
Figure 3. Format*



- *Total # of responses for hospital or health-system: small=4; medium=20; large=12. Total # of responses for MCO=8. For small hospitals or health-systems, medium hospitals or health-systems, and MCOs, the overall response was positive and customers were satisfied in reference to format
- Free text: One customer requested additional products in the Product
- For large hospitals or health-systems, customers were overall neutral (9/12) about the format.

RESULTS: Content

Figure 4. Content*



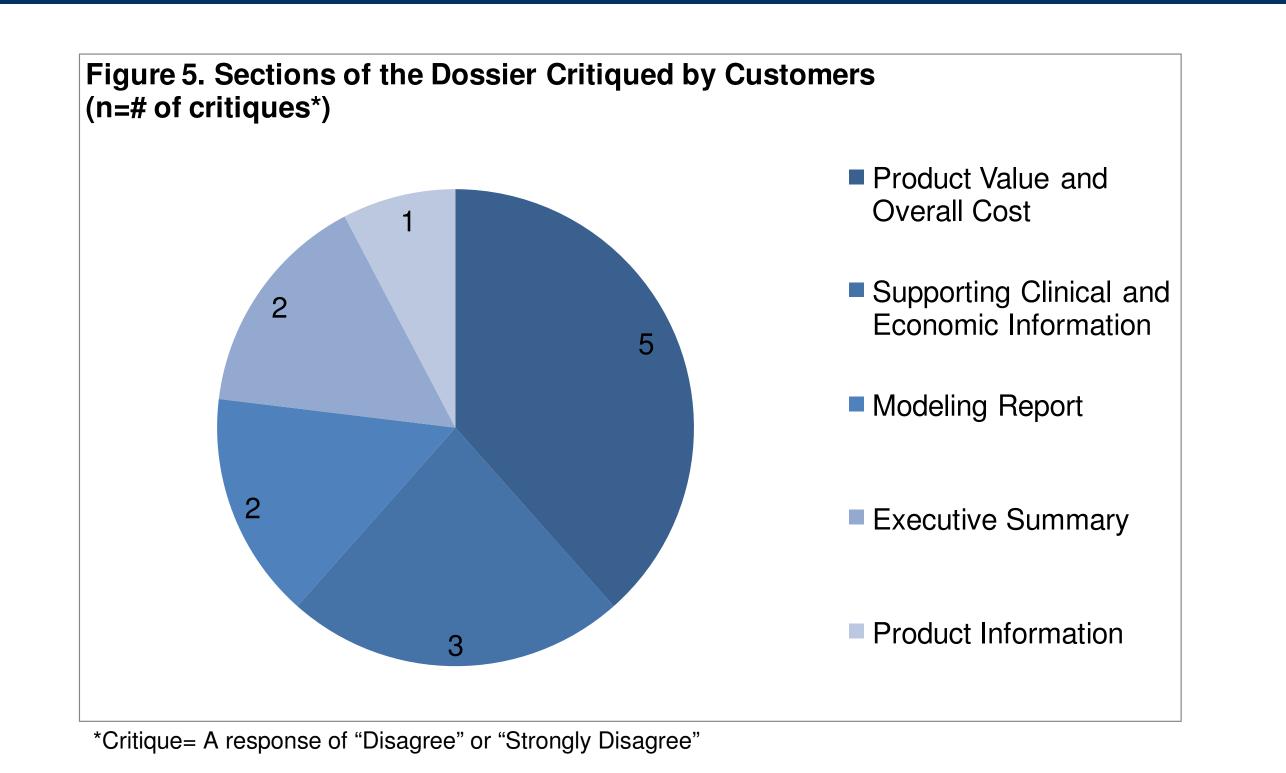
- Small hospital or health-system
- The one customer who responded was positive and satisfied with the overall
- He/she disagreed that the Product Value and Overall Cost section of the dossier was important and useful.
- Free text: Competitor product price was too high

Medium hospital or health-system

- Majority of responses were positive and customers were satisfied with the overall content.
- One customer disagreed that the Supporting Clinical and Economic Information and the Modeling Report sections were important and useful and strongly disagreed with the importance and usefulness of the Product Value and Overall Cost section.
- Customer disagreed with the importance and usefulness of this section when the question was asked again at the end of the survey.
- He/she disagreed that the Executive Summary reflected the most important contents of the dossier, the Product Information section was concise and helpful, and that the Supporting Clinical and Economic Information section contained the necessary data for a complete evaluation of the product.
- Large hospital or health-system
- Majority of responses were positive and customers were satisfied with the
- One customer disagreed that the Supporting Clinical and Economic Information section was important and useful and remained neutral about the Product Information section.
- Another customer disagreed that the Product Value and Overall Cost section of the dossier was important and useful. He/she remained neutral when asked if the Modeling Report section was fair and adequate and if the health economic models were comprehensible.
- The third customer remained neutral about the importance and usefulness of the Modeling Report.

Managed Care Organization

- Positive response to the <u>content</u>
- One customer disagreed that the Modeling Report and Product Value and Overall Cost sections of the dossier were important and useful.
- He/she also disagreed that the executive summary reflected the most important contents of the dossier.



RESULTS: Supporting Clinical and **Economic Information Section**

- Supporting Clinical and Economic Information section
- The majority of customers agreed additional information should be included in the Supporting Clinical and Economic Information section to conduct a complete evaluation of the product.

Figure 6. Information that Should be Included in the Supporting Clinical and

Economic Information Section (N=	:9)

	Agree/ Strongly Agree	Neither Agree nor Disagree	Disagree/ Strongly Disagree
Study funder	6	2	1
Potential biases	7	2	
Patient adherence results	7	2	
Grading of evidence	8	1	
Literature search criteria and criteria for exclusion of reviews/studies	8	1	
List of all trials undertaken for the product which have been submitted to the FDA	8	1	
Clinical study glossary	7	2	

RESULTS: Additional Questions

- Customers would consider distributing the following sections to staff for their educational or product review awareness
 - Executive Summary
- Product Information
- Overall Clinical Value
- Supporting Clinical and Economic Information
- Customers felt that the included reprints and posters were useful.
- No customer reported any strengths or weaknesses of the dossier.

DISCUSSION

- Revising the tapentadol IR dossier using feedback from the Advisory Board produced a dossier that received an overall positive response from customers.
- Due to the minimal free text responses, necessary actions to enhance sections that were unsatisfactory were not identified.
- Strategies to enhance customer response rate need to be evaluated.

LIMITATIONS

- The customer response rate was low with only 11 customers who participated.
- May be due to the lag time from when customers reviewed the dossier (late June to early October) and when they received the survey (early January)
- Three customers stopped responding towards the end of the survey; one customer chose neutral for the remainder of the survey. These results were included in the analysis.
- Not enough customers responded to draw conclusions based on customer type.
- Question assessing the importance and usefulness of the Product Value and Overall Cost section of the dossier was repeated.

CONCLUSIONS

- Customers were satisfied with the flow and format of the dossier. Customer satisfaction was more variable for the content of the dossier.
- Sections that should be enhanced are Supporting Clinical and Economic Information and Product Value and Overall Cost.
- Customers find value in adding additional information that is not required by the AMCP format in order to conduct a more thorough review of the product.

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